UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 20-F

☐ REGISTRATION STATEMENT PURSUANT TO SECTION 12(b) OR (g) OF THE SECURITIES EXCHANGE ACT OF 1934

OR

☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2024

OR

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

OR

☐ SHELL COMPANY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

Date of event requiring this shell company report _____

For the transition period from _____ to _____

Commission File No.: 001-38370

CollPlant Biotechnologies Ltd.
(Exact name of registrant as specified in its charter)

Translation of registrant's name into English: Not applicable

State of Israel	**4 Oppenheimer, Weizmann Science Park** **Rehovot 7670104, Israel** **Tel: +972 73 232 5600**
(Jurisdiction of incorporation or organization)	*(Address of principal executive offices)*

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Securities registered or to be registered pursuant to Section 12(b) of the Act:

Title of each class to be registered	**Trading Symbol(s)**	**Name of each exchange on which each class is to be registered**
Ordinary shares, par value NIS 1.50 per share	CLGN	Nasdaq Global Market

Securities registered or to be registered pursuant to Section 12(g) of the Act: None

Securities for which there is a reporting obligation pursuant to Section 15(d) of the Act: None

Number of outstanding shares of each of the issuer's classes of capital or common stock as of December 31, 2024: 11,454,512 ordinary shares.

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.

Yes ☐ No ☒

If this report is an annual or transition report, indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Exchange Act of 1934.

Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Exchange Act during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T during the preceding 12 months.

Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or an emerging growth company.

Large accelerated filer	☐	Accelerated filer	☐	Non-accelerated filer	☒
				Emerging Growth Company	☐

If an emerging growth company that prepares its financial statements in accordance with U.S. GAAP, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark which basis of accounting the registrant has used to prepare the financial statements included in this filing.

U.S. GAAP ☒

International Financial Reporting Standards as issued by the International Accounting Standards Board ☐

Other ☐

If "Other" has been checked in response to the previous question, indicate by check mark which financial statement item the registrant has elected to follow.

☐ Item 17 ☐ Item 18

If this is an annual report, indicate by check mark whether the registrant is a shell company.

Yes ☐ No ☒

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INTRODUCTION

We are a regenerative and aesthetic medicine company focused on medical aesthetics and 3D bioprinting of tissues and organs. Our products are based on our recombinant human collagen (rhCollagen) produced in genetically engineered tobacco plants using our proprietary technology. These products address indications for the diverse fields of tissue repair and aesthetics, and are ushering in a new era in regenerative and aesthetic medicine.

In February 2021, we entered into a development and global commercialization agreement with Allergan, an AbbVie company, or the AbbVie Development Agreement, pursuant to which we and AbbVie are collaborating in the development and commercialization of dermal and soft tissue filler product for the medical aesthetics market, using our rhCollagen technology in combination with AbbVie's technology. In February 2025, we announced the achievement of a development milestone with respect to this product candidate, which, according to the AbbVie Development Agreement, triggered a $2 million payment from AbbVie to us. This milestone achievement follows our announcement in June 2023 regarding another achievement of another major milestone, which triggered a $10 million payment from AbbVie to us. The dermal filler product candidate is currently in the clinical phase. AbbVie is collecting data and conducting a review of interim results from the first cohort of patients enrolled under the trials initiated in 2023 and next steps for the program are to be determined by AbbVie upon concluding their assessment. The trials are designed, planned, and executed by AbbVie.

In the field of medical aesthetics, we are developing regenerative 3D-bioprinted breast implants for regeneration of breast tissue to address an unmet need derived from estimated $3 billion global breast implant market. The implants in development are printed using bioink comprised of our rhCollagen in combination with other proprietary biomaterials. These implants are designed to regenerate breast tissue without eliciting immune response, and thus may provide a revolutionary alternative for aesthetic and reconstructive procedures. Pre-clinical studies continue to yield encouraging results. In August 2024, we launched a two-arm study utilizing a refined surgical protocol that enables implantation through a small incision while minimizing the risk of displacement or inversion. MRI and ultrasound analyses conducted in 2025 and 2024 confirmed tissue integration and vascularization, with one arm demonstrating rapid tissue ingrowth, preserved implant volume and mechanical integrity, and no observed complications. These outcomes support further optimization of the implants to promote long-term neo-tissue remodeling. In addition, we are developing a photocurable regenerative dermal filler comprised of our tissue regenerating rhCollagen and other biomaterials. In addition to skin lifting, this state-of-the-art filler is designed to enable skin rejuvenation as well as facial contouring, thus addressing the need for more innovative aesthetic products. In this regard, in early 2023 we completed a 12-month preclinical study with our photocurable regenerative dermal filler, demonstrating superior tissue regeneration, lifting capacity and volume retention when compared to a commercial standard.

In January 2023, we commercially launched Collink.3D 50L in powder form, which is our first bioink available in powder form, joining Collink.3D 90 and Collink.3D 50 launched in 2022 and 2021, respectively. Collink.3D is our rhCollagen-based bioink platform, which is ideal for 3D-bioprinting of tissues and organs for regenerative medicine applications. These rhCollagen-based bioink products are designed to allow the scalable and reproduceable biofabrication of scaffolds, tissues and organ transplants.

Our rhCollagen production process utilizes plant-based genetic engineering technology. This approach eliminates the need for traditional animal-derived collagen sources, reducing the environmental strain associated with traditional methods and promoting more ethical and sustainable practices.

On May 25, 2021, our ordinary shares were approved for trading on the Nasdaq Global Market and began trading at the open of market on June 4, 2021. At such time, our American Depositary Shares, or ADSs, each representing one ordinary shares, were mandatorily cancelled and exchanged for ordinary shares at a one-for-one ratio. Prior to that, our ADSs were quoted on the OTCQX from March 2015 to May 25, 2017, on the OTCQB from May 26, 2017 to January 30, 2018 and on the Nasdaq Capital Market from January 31, 2018 to June 3, 2021 under the symbol "CLGN". In 2018, we delisted our ordinary shares from trading on the Tel Aviv Stock Exchange, or TASE, and the last date of trading of our ordinary shares on the TASE was on October 29, 2018.

Unless the context requires otherwise, the terms "CollPlant," "we," "us," "our," "the Company," and similar designations refer to CollPlant Biotechnologies Ltd. and its subsidiaries, CollPlant Ltd. and CollPlant Inc. References to "ordinary shares", "warrants" and "share capital" refer to our ordinary shares, warrants and share capital, respectively, of CollPlant Biotechnologies Ltd.

Unless the context requires otherwise, references to "our products" refer also to products being developed by any strategic partner.

References to "U.S. dollars" and "$" are to currency of the United States of America, and references to "NIS" are to New Israeli Shekels. References to "ordinary shares" or "our ordinary shares" are to the ordinary shares of CollPlant Biotechnologies Ltd., par value NIS 1.50 per share. We report financial information under generally accepted accounting principles in the United States of America or U.S. GAAP.

The functional and presentation currency of the Company in this annual report on Form 20-F, or the Annual Report, is the U.S. dollar.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

Certain information included or incorporated by reference in this Annual Report on Form 20-F may be deemed to be "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995 and other securities laws. Forward-looking statements are often characterized by the use of forward-looking terminology such as "may," "will," "expect," "anticipate," "estimate," "continue," "believe," "should," "intend," "project" or other similar words, but are not the only way these statements are identified.

These forward-looking statements may include, but are not limited to, statements relating to our objectives, plans and strategies, statements that contain projections of results of operations or of financial condition, expected capital needs and expenses, statements relating to the research, development, completion and use of our products, and all statements (other than statements of historical facts) that address activities, events or developments that we intend, expect, project, believe or anticipate will or may occur in the future.

Forward-looking statements are not guarantees of future performance and are subject to risks and uncertainties. We have based these forward-looking statements on assumptions and assessments made by our management in light of their experience and their perception of historical trends, current conditions, expected future developments and other factors they believe to be appropriate.

Important factors that could cause actual results, developments and business decisions to differ materially from those anticipated in these forward-looking statements include, among other things:

- our history of significant losses, and our need to raise additional capital and our inability to obtain additional capital on acceptable terms, or at all;
- our expectations regarding the timing and cost of commencing pre-clinical and clinical trials with respect to rhCollagen based products in medical aesthetics and 3D bioprinting;
- ours or our strategic partners' ability to obtain favorable pre-clinical and clinical trial results;
- regulatory action with respect to rhCollagen based products in medical aesthetics and 3D bioprinting, including but not limited to acceptance of an application for marketing authorization, review and approval of such application, and, if approved, the scope of the approved indication and labeling;
- commercial success and market acceptance of rhCollagen based products in medical aesthetics and 3D bioprinting;
- our ability to establish sales and marketing capabilities or enter into agreements with third parties and our reliance on third party distributors and resellers;
- our ability to establish and maintain strategic partnerships and other corporate collaborations;

- our reliance on third parties to conduct some or all aspects of our product manufacturing;
- the scope of protection we are able to establish and maintain for intellectual property rights and our ability to operate our business without infringing the intellectual property rights of others;
- current or future unfavorable economic and market conditions and adverse developments with respect to financial institutions and associated liquidity risk;
- the impact of competition and new technologies;
- the overall global economic environment;
- statements as to the impact of the political and security situation in Israel on our business, including due to the current war between Israel and Hamas;
- projected capital expenditures and liquidity;
- changes in our strategy;
- litigation and regulatory proceedings; and
- those factors referred to in "Item 3.D. Risk Factors," "Item 4. Information on the Company," and "Item 5. Operating and Financial Review and Prospects", as well as in this Annual Report on Form 20-F generally.

Readers are urged to carefully review and consider the various disclosures made throughout this Annual Report on Form 20-F which are designed to advise interested parties of the risks and factors that may affect our business, financial condition, results of operations and prospects.

You should not put undue reliance on any forward-looking statements. Any forward-looking statements in this annual report on Form 20-F are made as of the date hereof and are expressly qualified in their entirety by the cautionary statements included in this Annual Report. We undertake no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

In addition, the section of this Annual Report on Form 20-F entitled "Item 4. Information on the Company" contains information obtained from independent industry sources and other sources that we have not independently verified.

EXPLANATORY NOTE

Market data and certain industry data and forecasts used throughout this Annual Report on Form 20-F were obtained from internal company surveys, market research, consultant surveys commissioned by the Company, publicly available information, reports of governmental agencies and industry publications and surveys. Industry surveys, publications, consultant surveys commissioned by the Company and forecasts generally state that the information contained therein has been obtained from sources believed to be reliable. However, this information may prove to be inaccurate because of the method by which some of the data for the estimates is obtained or because this information cannot always be verified with complete certainty due to the limits on the availability and reliability of raw data, the voluntary nature of the data gathering process and other limitations and uncertainties. As a result, the market and industry data and forecasts included or incorporated by reference in this annual report, and estimates and beliefs based on that data, may not be reliable. We have relied on certain data from third-party sources, including internal surveys, industry forecasts and market research, which we believe to be reliable based on our management's knowledge of the industry. However, we have not ascertained the underlying economic assumptions relied upon therein. Forecasts are particularly likely to be inaccurate, especially over long periods of time. In addition, we do not necessarily know what assumptions regarding general economic growth were used in preparing the forecasts we cite. Statements as to our market position are based to the best of our knowledge on the most currently available data. While we are not aware of any misstatements regarding the industry data presented in this Annual Report, our estimates involve risks and uncertainties and are subject to change based on various factors, including those discussed under the heading "Risk Factors" in this Annual Report.

Statements made in this Annual Report on Form 20-F concerning the contents of any agreement, contract or other document are summaries of such agreements, contracts or documents and are not a complete description of all of their terms. If we filed any of these agreements, contracts or documents as exhibits to this Report or to any previous filing with the Securities and Exchange Commission, or SEC, you may read the document itself for a complete understanding of its terms.

PART I

ITEM 1. IDENTITY OF DIRECTORS, SENIOR MANAGEMENT AND ADVISERS

Not applicable.

ITEM 2. OFFER STATISTICS AND EXPECTED TIMETABLE

Not applicable.

ITEM 3. KEY INFORMATION

A. Reserved.

B. Capitalization and Indebtedness

Not applicable.

C. Reasons for the Offer and Use of Proceeds

Not applicable.

D. Risk Factors

You should carefully consider the risks described below, together with all of the other information in this Annual Report on Form 20-F. The risks and uncertainties described below are those significant risk factors, currently known and specific to us, that we believe are relevant to an investment in our securities. Additional risks and uncertainties not currently known to us or that we now deem immaterial may also harm us. If any of these risks materialize, our business, results of operations or financial condition could suffer, and the price of our ordinary shares could decline substantially.

Summary Risk Factors

Investing in our ordinary shares involves a high degree of risk, as fully described below. The principal factors and uncertainties that make investing in our ordinary shares risky, include, among others:

Risks Related to Our Financial Position and Capital Requirements

- We have generally incurred significant losses since our inception and anticipate that we will continue to incur losses for the foreseeable future.
- We will need to raise additional funding, which may not be available on acceptable terms, or at all. Failure to obtain additional capital when needed may force us to delay, limit, or terminate our product development efforts or other operations.

Risks Related to Commercialization of Our Products

- The commercial success of any current or future product, if approved, will depend upon the degree of market acceptance by physicians, patients, third-party payors, pharma companies and others in the medical community.
- We have only limited clinical data to support sales of our products, which may make physicians, patients, third-party payors, and others in the medical community reluctant to accept or purchase our products.

- We have low scale experience in producing our rhCollagen, and if we are unable to manufacture our rhCollagen in high commercial quantities successfully and consistently to meet demand, our growth will be limited.

- If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to market and sell any of our products that obtain regulatory approval, we may be unable to generate material revenue.

- We face competition and rapid technological change and the possibility that our competitors may develop therapies or products that are more advanced or effective than ours, which could impair our ability to successfully commercialize our products.

Risks Related to the Clinical Development and Regulatory Approval of the Products

- We currently depend heavily on the future success of our medical aesthetics, 3D bioprinting product candidates and bioink products. Any failure to successfully develop, obtain regulatory approval for, and commercialize these products, independently or in cooperation with a third-party collaborator, or the experience of significant delays in doing so, would compromise our ability to generate revenue and become profitable.

- Our products are based on novel technology, which makes it difficult to predict the time and cost of product development and potential regulatory approval.

- We or our strategic partners may find it difficult to enroll patients in future clinical trials, and patients could discontinue their participation in our future clinical trials, which could delay or prevent clinical trials of our products and product candidates.

- Clinical trials conducted by us or by our strategic partners may not be successful or may be delayed.

- Even if we or our strategic partners obtain regulatory approval for a product, our products will remain subject to regulatory scrutiny.

- In addition to the level of commercial success of our products, our future prospects are also dependent on our ability to successfully develop a pipeline of additional products, and we may not be successful in our efforts in using our platform technologies to identify or discover additional products.

Risks Related to Our Reliance on Third Parties

- We may not be successful in establishing and maintaining strategic partnerships, which could adversely affect our ability to develop and commercialize our rhCollagen based products in 3D bioprinting and medical aesthetics, including 3D-bioprinted breast implants and bioinks.

- We expect to depend upon third-party collaborators, distributors and resellers for a significant portion of our sales.

- We expect to rely on third parties to conduct some aspects of our product manufacturing, protocol development, research, and preclinical and clinical testing, and these third parties may not perform satisfactorily.

Risks Related to Our Business Operations

- Our future success depends on our ability to retain senior management, consultants, and advisors and to attract, retain, and motivate qualified personnel.

- Our collaborations with outside scientists and consultants may be subject to restriction and change.

- Our business and operations would suffer in the event of computer system failures or security breaches.

- Our development and production of rhCollagen relies upon the continued availability of tobacco plants, and any interruption in availability or supply of tobacco plants may delay production and adversely affect commercial utilization of our rhCollagen-based products.

- If our existing rhCollagen production sites or any new facilities are damaged or destroyed, or production at these facilities is otherwise interrupted, our business and prospects would be negatively affected.

- If we fail to comply with environmental, health, and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse impact on the success of our business.

- We may use our financial and human resources to pursue a particular research program or product and fail to capitalize on programs or products that may be more profitable or for which there is a greater likelihood of success.

- Our business, operating results and growth rates may be adversely affected by current or future unfavorable economic and market conditions and adverse developments with respect to financial institutions and associated liquidity risk.

- Environmental, social and corporate governance (ESG) issues, including those related to climate change and sustainability, may have an adverse effect on our business, financial condition and results of operations and damage our reputation.

Risks Related to Our Intellectual Property

- We have an extensive worldwide patent portfolio. The cost of maintaining our worldwide patent protection is high and requires continuous review and compliance with procedural and documentary requirements. We may not be able to effectively maintain our intellectual property position throughout the major markets of the world.

- If we are unable to obtain or protect intellectual property rights related to our products and product candidates, we may not be able to obtain exclusivity for our products or prevent others from developing similar competitive products.

Risks Related to the Ownership of our Ordinary Shares

- The market price of our ordinary shares may be highly volatile.

- We may not be able to maintain our listing on the Nasdaq Global Market.

- Our principal shareholders, management and directors beneficially own a significant percentage of our ordinary shares and will be able to exert significant influence over matters subject to shareholder approval.

- If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, our shareholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our ordinary shares.

- Sales of a substantial number of our ordinary shares in the public market could cause our share price to fall.

Risks Related to Our Operations in Israel

- We are a "foreign private issuer" and intend to follow certain home country corporate governance practices, and our shareholders may not have the same protections afforded to shareholders of companies that are subject to all corporate governance requirements under the listing rules of the Nasdaq Stock Market LLC, or the Nasdaq Listing Rules.

- Potential political, economic, and military instability in the State of Israel, where the majority of our senior management and our research and development facilities are located, may adversely impact our results of operations.

Risks Related to Our Financial Position and Capital Requirements

We have generally incurred significant losses since our inception and anticipate that we will continue to incur losses for the foreseeable future.

We are a regenerative and aesthetic medicine company focused on medical aesthetics and 3D bioprinting of tissues and organs. Except for the year ended December 31, 2021, we have incurred losses in each year since our inception in 2004. We incurred a total comprehensive loss of $16.6 million for the year ended December 31, 2024 and a total comprehensive loss of $7.0 million for the year ended December 31, 2023. As of December 31, 2024, we had an accumulated deficit of $113.4 million.

We have devoted most of our financial resources to research and development, including our clinical and preclinical development activities. In recent years, we have financed our operations primarily with revenues from sales of our products, licensing of our technology, development milestone achievement payments from strategic partners as well as from net proceeds from private and public offerings. Prior to this, we financed our operations primarily from public offerings of our securities on the TASE, participation of business partners in product development collaborations, and government grants from the Israeli Innovation Authority, or the IIA. The amount of our future net losses will depend, in part, on the success of our collaborations and on the rate of our future expenditures. If and when we or our strategic partners will obtain regulatory approval to market products, our future revenues will depend upon the size of any markets in which the products have received approval, and the ability to achieve sufficient market acceptance, reimbursement from third-party payors and adequate market share for the products in those markets.

We expect to continue to incur significant expenses and operating losses in the foreseeable future. We anticipate that our expenses will increase substantially if and as we:

- continue our research and preclinical and clinical development of our products and product candidates;

- initiate additional preclinical, clinical, or other studies for our products and product candidates;

- seek marketing approvals for any of our products and product candidates that successfully complete clinical trials;

- further develop and expand the manufacturing process for our products and product candidates;

- establish a sales, marketing, and distribution infrastructure to commercialize our products and product candidates for which we may obtain marketing approval;

- seek to identify and validate additional products and product candidates;

- maintain, protect, and expand our intellectual property portfolio;

- attract and retain skilled personnel;

- create additional infrastructure to support our operations as a public company; and

- experience any delays or encounter issues with any of the above.

The net losses we incur may fluctuate significantly from quarter to quarter and year to year, such that a period-to-period comparison of our results of operations may not be a good indication of our future performance. In any particular quarter or quarters, our operating results could be below the expectations of securities analysts or investors, which could cause our share price to decline.

We will need to raise additional funding, which may not be available on acceptable terms, or at all. Failure to obtain additional capital when needed may force us to delay, limit, or terminate our product development efforts or other operations.

We are conducting preclinical development of our products and product candidates, and we intend to continue advancing their development. Developing medical products is expensive, and we expect our research and development expenses to continue to be a material part of our expenses and may increase substantially in connection with our ongoing activities, particularly as we or our strategic partners advance our products or product candidates in clinical trials.

As of December 31, 2024, our cash and cash equivalents were $11.9 million. Although in the past we have received payments under the AbbVie Development Agreement, including a $2 million in February 2025, $10 million in June 2023 and $14 million in February 2021, there can be no assurance that we will receive any further payments under the AbbVie Development Agreement. Except for the year ended December 31, 2021, in which we incurred a total comprehensive income of $0.2 million, we had recurring losses from operations and negative operating cash flows since our inception. We recently implemented a cost cutting and workforce reduction plan and will need to raise additional capital in the future to support our operations and product development activities,

Our operating plan may change as a result of many factors currently unknown to us, and we may need to seek additional funds sooner than planned, through public or private equity or debt financings, third-party funding, marketing and distribution arrangements, and other collaborations, strategic alliances, and licensing arrangements, or a combination of these approaches. Even if we believe we have sufficient funds for our current or future operating plans, we may seek additional capital if market conditions are favorable or if we have specific strategic considerations. Conversely, we may need to seek additional funds at times when the market conditions for doing so are less favorable. Any debt financing obtained by us could involve restrictive covenants relating to financial and operational matters, which may make it more difficult for us to obtain additional capital and to pursue business opportunities and could require us to use a portion of our cash flows to make debt service payments, which could place us at a competitive disadvantage relative to our less leveraged peers. If we raise additional funds through further issuances of equity, convertible debt securities, or other securities convertible into equity, our existing stockholders could suffer significant dilution in their percentage ownership of our company, and any new equity securities we issue could have rights, preferences, and privileges senior to those of holders of our common stock, including registration rights. If we are unable to obtain adequate financing or financing on terms satisfactory to us when we require it, our ability to support our business and to respond to business challenges could be significantly limited, and our business, operating results, financial condition, and prospects could be harmed.

Any additional fundraising efforts may divert our management from their day-to-day activities, which may compromise our ability to develop and commercialize our products and product candidates. In addition, we cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. Moreover, the terms of any financing may adversely affect the holdings or the rights of our shareholders, and the issuance of additional securities, whether equity or debt, by us, or the possibility of such issuance, may cause the market price of our ordinary shares to decline. The sale of additional equity or convertible securities would dilute all of our shareholders. The incurrence of indebtedness would result in increased fixed payment obligations, and we may be required to agree to certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell, or license intellectual property rights, and other operating restrictions that could adversely impact our ability to conduct our business. We could also be required to seek funds through arrangements with collaborative partners or otherwise at an earlier stage than otherwise would be desirable, and we may be required to relinquish rights to some of our technologies or products or otherwise agree to terms unfavorable to us.

If additional capital is not available to us when needed or on acceptable terms, we may be required to significantly curtail, delay, or discontinue one or more of our research or development programs or the commercialization of any products or product candidates, and we may be unable to expand our operations or otherwise capitalize on our business opportunities, as desired.

The IIA grants we have received in the past for research and development expenditures may restrict our ability to manufacture products and transfer IIA funded know-how outside of Israel and require us to satisfy specified conditions.

Our research and development efforts have been financed, in part, through the grants that we have received in the past from the IIA. We, therefore, must comply with the requirements of, and are subject to certain restrictions under, the Israeli Encouragement of Research, Development and Technological Innovation in the Industry Law of 1984, or the Innovation Law and the IIA's rules and guidelines with respect to the use of intellectual property and other know-how resulting, directly or indirectly, in whole or in part, in accordance with or as a result of, research and development activities made according to a research and development program funded by the IIA, or the Approved Program, as well as any rights associated with such know-how (including later developments, which derive from, are based on, or constitute improvements or modifications of such know-how), or the IIA Funded Know-How. These restrictions involve obligations relating to royalty payments, reporting and local manufacturing, and limitations on the transfer of IIA Funded Know-How and the licensing of IIA Funded Know-How for research and development, or R&D, purposes.

Such restrictions may impair our ability to perform or outsource manufacturing rights outside of Israel, granting licenses for R&D purposes or otherwise transfer outside of Israel our IIA Funded Know-How. These restrictions may also require us to obtain the approval of the IIA for certain actions and transactions and pay additional royalties and other amounts to the IIA. We cannot be certain that any approval of the IIA will be obtained on terms that are acceptable to us, or at all. Furthermore, the consideration available to our shareholders in a transaction involving the transfer outside of Israel of IIA Funded Know-How (such as a merger or similar transaction) or a transaction involving the licensing of IIA Funded Know-How for R&D purposes outside of Israel, may be reduced by any amounts that we are required to pay to the IIA.

If we fail to comply with the requirements of the Innovation Law, we may be subject to financial sanctions, to mandatory repayment of grants received by us (together with interest and penalties), as well as expose us to criminal proceedings. For additional information regarding the Innovation Law and the IIA, see "Item 4.B. Business Overview—Other Approvals—The Innovation Law and the IIA".

Until 2019 we have applied and received grants from the IIA as part of the research and development programs for our rhCollagen technology and our products. These IIA grants are subject to repayment through future royalty payments on any products resulting from these research and development programs, including VergenixSTR and VergenixFG. Under the IIA's rules and guidelines royalties of 3% on the income deriving from products and from related know-how and services developed in whole or in part, directly or indirectly, under the Approved Programs are payable to the IIA, up to the total amount of grants received, linked to the U.S. dollar plus interest at an annual rate based on based on LIBOR. The total gross amount of grants actually received by us from the IIA as of December 31, 2024 totaled approximately $10.1 million. As of December 31, 2024, we paid royalties to the IIA in the total amount of $3.1 million.

We may not be able to correctly estimate or control our future operating expenses, which could lead to cash shortfalls.

Our operating expenses may fluctuate significantly in the future for various reasons, many of which are outside of our control. These reasons may include:

- the time, resources, and expenses required to conduct pre-clinical and clinical trials of, seek regulatory approvals for, manufacture, market, and sell our current products and any additional products we may develop;

- the time, resources, and expenses required to research and develop additional indications of our current products;
- the costs of preparing, filing, prosecuting, defending, and enforcing patent claims and other patent-related costs, including litigation costs or the results of such litigation;
- any product liability or other lawsuits related to our products and the costs associated with defending them or the results of such lawsuits;
- the costs to attract and retain personnel with the skills required for effective operations; and
- the costs associated with being a public company in the United States.

It is difficult to forecast our future performance, which may cause our financial results to fluctuate unpredictably.

Because we do not yet have an established commercial operating history, and because the market for our products and product candidates may rapidly evolve, it is hard for us to predict our future performance. A number of factors, many of which are outside of our control, may contribute to fluctuations in our financial results assuming that we receive marketing authorizations and begin selling our products. These factors may include variations in:

- market demand for, and acceptance of, our products;
- our ability to obtain or maintain regulatory approvals;
- our sales and marketing operations, or the effectiveness of these operations;
- performance of our third-party contractors;
- the availability of procedures or products that compete with our products;
- media coverage of our technologies, the procedures or products of our competitors or our industry; and
- natural disasters and political and economic instability, including wars, terrorism, political unrest, results of certain elections and votes, emergence of a pandemic, or other widespread health emergencies (or concerns over the possibility of such an emergency), boycotts, adoption or expansion of government trade restrictions, and other business restrictions).

Risks Related to Commercialization of Our Products

The commercial success of any current or future product, if approved, will depend upon the degree of market acceptance by physicians, patients, third-party payors, pharma and medical device companies and others in the medical community.

Even if we or our strategic partners obtain the requisite regulatory approvals, the commercial success of our products will depend in part on physicians, patients, third party payors, pharma and medical device companies and others in the medical community accepting our products as medically useful, cost-effective, and safe. Any product that we or our strategic partners bring to the market may not gain market acceptance by physicians, patients, third-party payors, and others in the medical community. If these products do not achieve an adequate level of acceptance, we may not generate significant product revenue and may not become profitable. The degree of market acceptance of these products, if approved for commercial sale, will depend on a number of factors, including:

- the cost, safety, efficacy, and convenience of our products in relation to alternative treatments and products;
- the ability of third parties to enter into relationships with us without violating their existing agreements;

- the effectiveness of our sales and marketing efforts;
- the prevalence and severity of any side effects, including any limitations or warnings contained in a product's approved labeling;
- the prevalence and severity of any side effects resulting from the procedure by which our products are administered;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the strength of marketing and distribution support for, and timing of market introduction of, competing products;
- publicity concerning our products or competing products and treatments; and
- sufficient third-party insurance coverage or reimbursement.

Even if a potential product displays a favorable safety and efficacy profile in clinical trials, market acceptance of the product will not be known until after it is launched. Our efforts or those of our strategic partners to educate the medical community and third-party payors on the benefits of the products may require significant resources and may never be successful. Such efforts to educate the marketplace may require more resources than are required by conventional technologies.

We have only limited clinical data to support sales of our products, which may make physicians, patients, third-party payors, and others in the medical community reluctant to accept or purchase our products.

Physicians, patients, third party payors, and others in the medical community will only accept or purchase our products if they believe them to be safe and effective, with advantages over competing products or procedures. To date, we have collected only limited clinical data with which to assess the clinical and economic value of VergenixFG and VergenixSTR. The collection of clinical and economic data and the process of generating peer review publications in support of our product and procedure is an ongoing focus for us. If future publications of clinical studies indicate that procedures using our products, or other products that contains our rhCollagen, are less safe or less effective than competing products or procedures, patients may choose not to undergo our procedure, and physicians or others in the medical community may choose not to use our products. Furthermore, unsatisfactory patient outcomes or patient injury could cause negative publicity for our products, particularly in the early phases of product introduction.

We have low scale experience in producing our rhCollagen, and if we are unable to manufacture our rhCollagen in high commercial quantities successfully and consistently to meet demand, our growth will be limited.

We have experience manufacturing limited quantities of rhCollagen, the recombinant human type I collagen used for development with collaborators and in our products and product candidates. Our manufacturing capabilities will need to be further improved to meet the standard requirements for future clinical studies and for commercialization of our products and product candidates. To manufacture our rhCollagen in quantities that we believe will be sufficient to produce our end products and meet anticipated market demand, we will need to increase manufacturing capacity or engage third party manufacturers, which will involve significant challenges. In addition, the development of commercial-scale, regulation-compliant manufacturing capabilities will require us to invest substantial additional funds and our efforts to establish these capabilities may not meet our requirements as to scale-up, yield, cost, potency, or quality in compliance with applicable regulatory standards. Even an experienced third-party manufacturer may encounter difficulties in production, including:

- costs and challenges associated with scale-up and attaining sufficient manufacturing yields;
- supply chain issues, including the timely availability and shelf-life requirements of raw materials and supplies;

- quality control and assurance;
- shortages of qualified personnel and capital required to manufacture large quantities of product;
- compliance with regulatory requirements that vary in each country where a product might be sold;
- capacity limitations and scheduling availability in contracted facilities; and
- natural disasters or war and terrorism that affect facilities and possibly limit production.

The regulatory authorities also may, at any time following approval of a product for sale, audit our manufacturing facilities or those of our third-party contractors. If any such inspection or audit identifies a failure to comply with applicable regulations or our product specifications or if a violation of applicable regulations, including a failure to comply with the product specifications, occurs independent of such an inspection or audit, we or the relevant regulatory authority may require remedial measures that may be costly or time consuming for us or a third party to implement and that may include the temporary or permanent suspension of a clinical trial or commercial sales or the temporary or permanent closure of a facility.

If we or any of any third-party manufacturer fails to maintain regulatory compliance, the FDA or the European authorities can impose regulatory sanctions including, among other things, refusal to approve a pending application for a new product or revocation of a pre-existing approval.

If there is a disruption to our internal manufacturing operations, we will have no other means of production for the components and products from such operations until we restore the affected facilities or develop alternative manufacturing facilities, which would delay our or our strategic partners' clinical trials or cause us to be unable to meet commercial demand for our products. In such case, we may need to arrange for third-party manufacturing of our components and products, which would be expensive and time consuming, assuming we can identify an appropriate third party manufacturer. Additionally, any damage to or destruction of our facilities or equipment may significantly impair our ability to manufacture our components and products on a timely basis. During early 2024, we had a mechanical failure at our Yessod Hama'ala facility that occurred during the production process resulting in the temporary shutdown of our manufacturing operations. In addition, during 2024, we took precautionary measures to close our facility in Yessod Hama'ala for an extended period, although it is now operational, due to the war and its proximity to the border with Lebanon. See "—Risks Related to Our Operations in Israel — Potential political, economic, and military instability in the State of Israel, where the majority of our senior management and our research and development facilities are located, may adversely impact our results of operations."

If we are unable to produce our products in sufficient quantities to meet anticipated customer demand, our revenues, business, and financial prospects would be harmed. The lack of experience we have in producing commercial quantities of our components and products may also result in quality issues and product recalls. Any product recall could be expensive and generate negative publicity, which could impair our ability to market our products and further affect our results of operations. Manufacturing delays related to quality control could negatively impact our ability to bring our technologies to market, harm our reputation, and decrease our revenues.

Any delay or interruption in the supply of our products could have a material adverse effect on our business and operations.

If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to market and sell any of our products, we may be unable to generate material revenue.

We have limited experience in selling and marketing our products or any other products. To successfully commercialize our products, we will need to develop these capabilities, either on our own or with others. We are seeking to enter commercial alliances with third-party collaborators and distributors to utilize their development, marketing and distribution capabilities, but we may be unable to do so on favorable terms, if at all. If any future collaboration or distribution partners do not commit sufficient resources to commercialize our future products, and if we are unable to develop the necessary marketing capabilities on our own, we will be unable to generate sufficient product revenue to sustain our business. We will be competing with many companies that currently have extensive and well-funded marketing and sales operations. Without an internal team or the support of a third party to perform marketing and sales functions, we may be unable to compete successfully against these more established companies or successfully commercialize any of our products.

We face competition and rapid technological change and the possibility that our competitors may develop therapies or products that are more advanced or effective than ours, which could impair our ability to successfully commercialize our products.

We operate in the regenerative and aesthetic medicine fields, which are rapidly changing. We have competitors both in the United States and internationally, including major multinational pharmaceutical companies, biotechnology companies, medical technology companies, and universities and other research institutions.

Many of our potential competitors have substantially greater financial, technical and other resources, such as larger research and development staff and experienced marketing and manufacturing organizations. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Our potential competitors may succeed in developing, acquiring, or licensing on an exclusive basis, products that are more effective or less costly than any products that we may develop, or achieve earlier patent protection, regulatory approval, product commercialization, and market penetration than us. Additionally, technologies developed by others may render our potential products uneconomical or obsolete, and we may not be successful in marketing our products against competitors.

We are not aware of any competitors that produce collagen from plants or that produce recombinant type I human collagen.

A variety of risks associated with international operations could harm our business.

Our intention is to market our products on a regional or worldwide basis, either alone or in collaboration with third parties. In addition, we may conduct development activities in various jurisdictions throughout the world. We expect that we will be subject to additional risks related to engaging in international operations, including:

- different regulatory requirements for product approval in foreign countries;
- reduced protection for intellectual property rights;
- unexpected changes in tariffs, trade barriers, and regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration, and labor laws for employees living or traveling abroad;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- workforce uncertainty in countries where labor unrest is more common than in the United States and Israel;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geopolitical actions, including war and terrorism, or natural disasters including earthquakes, typhoons, floods, fires, emergence of a pandemic, or other widespread health emergencies (or concerns over the possibility of such an emergency).

The insurance coverage and reimbursement status of newly approved products is uncertain. Failure to obtain or maintain adequate coverage and reimbursement for any of our products could limit our ability to market those products and compromise our ability to generate revenue.

The availability of reimbursement by governmental and private payors is essential for most patients to be able to afford expensive treatments. Sales of our products will depend substantially, both in Europe and in the United States, on the extent to which the costs of our products will be paid by health maintenance organizations, managed care, pharmacy benefit managers, and similar healthcare management organizations, or reimbursed by government health administration authorities, private health coverage insurers, and other third-party payors. If reimbursement is not available, or is available only to limited levels, we may not be able to successfully commercialize our products. Even if we obtain coverage for our products, third-party payors may not establish adequate reimbursement amounts, which may reduce the demand for, or the price of, our products. If reimbursement is not available or is available only to limited levels, we may not be able to commercialize certain of our products.

Furthermore, publication of discounts by third-party payors or authorities may lead to further pressure on the prices or reimbursement levels within the country of publication and other countries. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unacceptable levels, we or our partner may elect not to commercialize our products in such countries, and our business and financial condition could be adversely affected.

Promotion of off-label uses of our products by physicians could adversely affect our business.

Any regulatory approval of our products is limited to those specific indications for which our products have been deemed safe and effective by the regulatory authorities. In addition, any new indication for an approved product also requires regulatory approval. If we produce an approved product, we will rely on physicians to use and administer it as we have directed and for the indications described on the labeling. It is not, however, uncommon for physicians to use in unapproved, or "off-label," uses or in a manner that is inconsistent with the manufacturer's directions. To the extent such off-label uses and departures from our administration directions become pervasive and produce results such as reduced efficacy or other adverse effects, the reputation of our products in the marketplace may suffer. In addition, off-label uses may cause a decline in our revenue or potential revenue, to the extent that there is a difference between the prices of our product for different indications.

Furthermore, while physicians may choose to use our products for off-label uses, our ability to promote the products is limited to those indications that are specifically approved by the regulators. Although regulatory authorities generally do not regulate the behavior of physicians, they do restrict communications by companies with respect to off-label use. If our promotional activities fail to comply with these regulations or guidelines, we may be subject to warnings from, or enforcement action by, these authorities. In addition, failure to follow regulation authorities' rules and guidelines relating to promotion and advertising can result in the regulation authorities' refusal to approve a product, the suspension or withdrawal of an approved product from the market, product recalls, fines, disgorgement of money, operating restrictions, injunctions, or criminal prosecution.

Risks Related to the Clinical Development and Regulatory Approval of Our Products

We currently depend heavily on the future success of our medical aesthetics, 3D-bioprinting product candidates and our bioink products. Any failure to successfully develop, obtain regulatory approval for, and commercialize these products, independently or in cooperation with a third-party collaborator, or the experience of significant delays in doing so, would compromise our ability to generate revenue and become profitable.

We have invested a significant portion of our efforts and financial resources in the development of rhCollagen, medical aesthetics and 3D-bioprinting product candidates, bioinks and our Vergenix line of products. We currently depend heavily on the future success of our medical aesthetics, 3D-bioprinting product candidates and our bioink products. Our ability to generate revenues from our products and product candidates depends heavily on the successful development, approval, and commercialization of our products, which, in turn, depend on several factors, including the following:

- our ability to continue and support our rhCollagen platform technology and programs;

- our ability to establish and maintain strategic partnerships, including the AbbVie Development Agreement;
- our or our strategic partners successfully initiating and completing preclinical, clinical and other studies required for our products and product candidates;
- demonstrating and maintaining the safety and efficacy of our products at a sufficient level of statistical or clinical significance and otherwise obtaining marketing approvals from regulatory authorities;
- establishing successful sales and marketing arrangements for our products;
- the availability of coverage and reimbursement by healthcare payors for our products in the jurisdictions where they may be approved;

Our products are based on novel technology, which makes it difficult to predict the time and cost of product development and potential regulatory approval.

We have concentrated our product research and development efforts on our novel rhCollagen technology. The FDA has approved very few plant-expressed products. We may experience development challenges in the future related to our technology, which could cause significant delays or unanticipated costs, and we may not be able to solve such development challenges. We may also experience delays in developing a sustainable, reproducible, and scalable manufacturing process or transferring that process to commercial partners, if we decide to do so.

In addition, the clinical trial requirements of European regulatory authorities, the FDA, and other regulatory authorities and the criteria these regulators use to determine the safety and efficacy of a product vary substantially according to the type, complexity, novelty, and intended use and market of the potential products. The regulatory approval process for novel products such as ours can be more expensive and take longer than for other, better known or extensively studied products. Our products may also be designated by the FDA or other regulatory authorities as combination products, which include: (1) a product comprised of two or more regulated components, e.g., drug/device, biologic/device, drug/biologic, or drug/device/biologic, that are physically, chemically, or otherwise combined or mixed and produced as a single entity; (2) two or more separate products packaged together in a single package or as a unit and comprised of drug and device products, device and biological products, or biological and drug products; (3) a drug, device, or biological product packaged separately that according to its investigational plan or proposed labeling is intended for use only with an approved individually specified drug, device, or biological product where both are required to achieve the intended use, indication, or effect and where upon approval of the proposed product the labeling of the approved product would need to be changed, e.g., to reflect a change in intended use, dosage form, strength, route of administration, or significant change in dose; or (4) any investigational drug, device, or biological product packaged separately that according to its proposed labeling is for use only with another individually specified investigational drug, device, or biological product where both are required to achieve the intended use, indication, or effect. Combination Products containing a biologic/device then may be regulated as a biologic product, resulting in a longer regulatory approval process than the regulatory approval process for a medical device alone. Approvals by any regulatory authorities may not be indicative of what the FDA or other regulatory agencies may require for approval, and vice versa.

Regulatory requirements governing medical devices and other products for medical use have changed frequently and may continue to change in the future. Also, before a clinical trial can begin, an institutional review board, or IRB, at each institution at which a clinical trial will be performed must review the proposed clinical trial to assess the safety of the trial. In addition, adverse developments in clinical trials of comparable products conducted by others may cause European regulatory authorities, the FDA, or other regulatory authorities to change the requirements for approval of any of our products.

These regulatory agencies and additional or new requirements may lengthen the regulatory review process, require us to perform additional studies, increase our development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of our products, or lead to significant approval and post-approval limitations or restrictions. As we advance our products, we will be required to consult with these regulatory authorities, and comply with applicable requirements. If we fail to do so, we may be required to delay or discontinue development of our products. Delay or failure to obtain, or unexpected costs in obtaining, the regulatory approval necessary to bring a potential product to market could impair our ability to generate product revenue and to become profitable.

We or our strategic partners may find it difficult to enroll patients in clinical trials, and patients could discontinue their participation in clinical trials, which could delay or prevent clinical trials of our products and product candidates.

Identifying and qualifying patients to participate in clinical trials of our products and product candidates is critical to our success. The timing of clinical trials depends on the ability to recruit patients to participate in our or our strategic partners' clinical trials. We or our strategic partners may experience delays in patient enrollment in the future. If patients are unwilling to participate in clinical trials because of negative publicity from adverse events in the biotechnology, pharmaceutical or medical technology industries, or for other reasons, including competitive clinical trials for similar patient populations, the timeline for recruiting patients, conducting trials, and obtaining regulatory approval of potential products may be delayed. These delays could result in increased costs, delays in advancing our product development, delays in testing the effectiveness of our technology, or termination of the clinical trials altogether.

We or our strategic partners may not be able to identify, recruit, and enroll a sufficient number of patients, or those with required or desired characteristics to achieve diversity in a trial, to complete clinical trials in a timely manner, or at all. Patient enrollment is affected by factors including:

- design of the trial protocol;
- size of the patient population;
- eligibility criteria for the trial in question;
- severity of the disease/wounds under investigation;
- perceived risks and anticipated benefits of the product under study;
- proximity and availability of clinical trial sites for prospective patients;
- availability of competing therapies, products, and clinical trials;
- efforts to facilitate timely enrollment in clinical trials;
- patient referral practices of physicians; and
- ability to monitor patients adequately during and after treatment.

While we are currently not conducting any clinical trials, the dermal and soft tissue filler product candidate for the medical aesthetics market is in the clinical phase, and the trials are designed, planned, and executed by AbbVie, in accordance with the AbbVie Development Agreement. We and/or our strategic partners may not be able to initiate or continue future clinical trials if a sufficient number of eligible patients to participate in the clinical trials required by European regulatory authorities, the FDA, or other regulatory authorities cannot be enrolled.

In addition, patients enrolled in ours, or our strategic partners' clinical trials may discontinue their participation at any time during the trial as a result of a number of factors, including withdrawing their consent or experiencing adverse clinical events, which may or may not be related to our products under evaluation. The discontinuation of patients in any one of the trials may cause delay or abandonment of such clinical trial, or cause the results from that trial not to be positive or sufficient to support a filing for regulatory approval of the applicable product.

Clinical trials conducted by us or our strategic partners may not be successful or may be delayed.

Before obtaining marketing approval from regulatory authorities for the sale of our products or product candidates or any future product, we or our strategic partners must conduct clinical trials to demonstrate the safety in humans for European CE marking certification, and the safety and efficacy in humans for other regulatory authorities such as the United States. While we are currently not conducting any clinical trials, the dermal and soft tissue filler product candidate for the medical aesthetics market is in the clinical phase, and the trials are designed, planned, and executed by AbbVie. AbbVie is collecting data and conducting a review of interim results from the first cohort of patients enrolled under the trials initiated in 2023 and next steps for the program are to be determined by AbbVie upon concluding their assessment. In addition, we expect to rely on a number of contract research organizations, or CROs, and other third parties, to assist in undertaking, managing, monitoring, and executing future clinical trials. Clinical trials are expensive, time consuming, and uncertain as to outcome. We cannot guarantee that any clinical trials will be conducted as planned or completed on schedule, if at all. We or our strategic partners may not receive FDA regulatory approval for the conduct of any particular clinical trial in the United States or regulatory approval for conduct of such clinical trial in other countries. A failure of one or more clinical trials can occur at any stage of testing. Events that may prevent successful or timely completion of clinical development include:

- delays in reaching a consensus with regulatory agencies on trial design;
- delays in reaching agreement on acceptable terms with prospective CROs and clinical trial sites;
- delays in obtaining required IRB approval at each clinical trial site;
- delays in recruiting suitable patients to participate in our clinical trials;
- failure by our strategic partners, CROs, other third parties or us to perform in accordance with clinical trial requirements or the FDA's good clinical practices, or GCP, or applicable regulatory requirements in other countries;
- delays in the testing, validation, manufacturing, and delivery of our products to the clinical sites;
- delays in having patients complete participation in a trial or return for post-treatment follow-up;
- clinical trial sites or patients dropping out of a trial;
- occurrence of serious adverse events associated with the products that are viewed to outweigh their potential benefits; or
- changes in regulatory requirements and guidance that require amending or submitting new clinical trial protocols.

Any inability to successfully complete preclinical and clinical development could result in additional costs to us or impair our ability to generate revenue from product sales, milestone payments or royalties. In addition, if we or our strategic partners make manufacturing or design changes to our products or product candidates, additional studies may be required to bridge our modified products to earlier versions. Clinical trial delays could also shorten any periods during which we may have the exclusive right to commercialize our products or product candidates or allow our competitors to bring products to market before we do, which could impair our ability to successfully commercialize our products.

If the results of clinical trials are inconclusive or if there are safety concerns or adverse events associated with our products or product candidates, we or our strategic partners may:

- fail to obtain, or be delayed in obtaining, marketing approval for our products or product candidates;
- obtain approval for indications or patient populations that are not as broad as intended or desired;

- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings;
- be required to perform additional clinical trials to support approval or be subject to additional post-marketing testing requirements;
- have regulatory authorities withdraw their approval of the product or impose restrictions on its distribution;
- be subject to the addition of labeling statements, such as warnings or contraindications;
- terminate any ongoing collaboration agreement;
- be sued; or
- experience damage to our reputation.

Any of these events could prevent us from achieving or maintaining market acceptance of our products or product candidates and impair our ability to commercialize our products.

Success in early clinical trials may not be indicative of results obtained in later trials.

There is a high failure rate for medical devices, drugs, and biologics proceeding through clinical trials. A number of companies in the pharmaceutical, biotechnology, and medical technology industries have suffered significant setbacks in later stage clinical trials even after achieving promising results in earlier stage clinical trials. Data obtained from preclinical and clinical activities are subject to varying interpretations, which may delay, limit, or prevent regulatory approval. In addition, regulatory delays or rejections may be encountered as a result of many factors, including the novelty of the product and changes in regulatory policy during the period of product development.

Even if we or our strategic partners complete the necessary preclinical studies and clinical trials, we cannot predict when or if we will obtain regulatory approval to commercialize a product, or the approval may be for a more narrow indication than we expect.

We or our strategic partners cannot commercialize a product until the appropriate regulatory authorities have reviewed and approved the product. Even if our products or product candidates demonstrate safety and efficacy in clinical trials, the regulatory agencies may not complete their review processes in a timely manner, or we may not be able to obtain regulatory approval. Additional delays may result if an FDA Advisory Committee or other regulatory authority recommends non-approval or restrictions on approval. In addition, we may experience delays or rejections based upon additional government regulation from future legislation or administrative action, or changes in regulatory agency policy during the period of product development, clinical trials, and the review process. Regulatory agencies also may approve a treatment for fewer or more limited indications than requested or may grant approval subject to the performance of post-marketing studies. In addition, regulatory agencies may not approve the labeling claims that are necessary or desirable for the successful commercialization of our treatment.

Side effects may occur following treatment with our products or product candidates which could make it more difficult for our products to receive regulatory approval.

Treatment with our products or product candidates may cause side effects or other adverse events. In addition, since our products may be administered in combination with other therapies, patients or clinical trial participants may experience side effects or other adverse events that are unrelated to our product, but may still impact the success of our clinical trials. Additionally, our products or product candidates could potentially cause other adverse events that have not yet been predicted. The experience of side effects and adverse events in our clinical trials could make it more difficult to achieve regulatory approval of our products or, if approved, could negatively impact the market acceptance of such products.

Even if we or a strategic partner obtains regulatory approval for a product, our products will remain subject to regulatory scrutiny.

Even if we or a strategic partner obtain regulatory approval in a jurisdiction, the regulatory authority may still impose significant restrictions on the indicated uses or marketing of our products, or impose ongoing requirements for potentially costly post-approval studies or post-market surveillance. Advertising and promotional materials must comply with FDA, Federal Trade Commission, or FTC, and European and other countries' regulatory requirements and are subject to review by the FDA, FTC or other governmental authorities, in addition to other potentially applicable federal and state laws.

The laws that may affect our operations in the United States include:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering, or paying remuneration, directly or indirectly, to induce, or in return for, the purchase or recommendation of an item or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs;

- federal civil and criminal false claims laws and civil monetary penalty laws, which prohibit, among other things, individuals, or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payors that are false or fraudulent;

- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created new federal criminal statutes that prohibit executing a scheme to defraud any healthcare benefit program and making false statements relating to healthcare matters;

- HIPAA, as amended by the Health Information Technology and Clinical Health Act, or HITECH, and its implementing regulations, which imposes certain requirements relating to the privacy, security, and transmission of individually identifiable health information;

- the federal physician sunshine requirements under the Patient Protection and Affordable Care Act, which requires manufacturers of drugs, devices, biologics, and medical supplies to report annually to the Centers for Medicare and Medicaid Services, or CMS, information related to payments and other transfers of value to physicians, other healthcare providers, and teaching hospitals, and ownership and investment interests held by physicians and other healthcare providers and their immediate family members; and

- foreign and state law equivalents of each of the above federal laws, such as the U.S. Foreign Corrupt Practices Act, or the FCPA, and anti-kickback and false claims laws that may apply to items or services reimbursed by any third-party payor, including commercial insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws that require manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways, thus complicating compliance efforts.

The scope of these laws and our lack of experience in establishing the compliance programs necessary to comply with this complex and evolving regulatory environment increase the risks that we may violate the applicable laws and regulations.

In addition, product manufacturers and their facilities are subject to continual review and periodic inspections by the European regulatory authorities, the FDA, and other regulatory authorities for compliance with cGMP or any applicable European or other governmental regulations. If we or a regulatory agency discover previously unknown problems with a product such as adverse events of unanticipated severity or frequency or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions relative to that product or the manufacturing facility, including requiring recall or withdrawal of the product from the market or suspension of manufacturing.

If we fail to comply with applicable regulatory requirements following approval of any of our products, one or more regulatory authorities could:

- issue a warning letter asserting that we are in violation of the law;
- seek an injunction or impose civil or criminal penalties or monetary fines;
- suspend or withdraw regulatory approval;
- suspend any ongoing clinical trials;
- seize our product; or
- refuse to allow us to enter into supply contracts, including government contracts.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity and potentially lead to private litigation. The occurrence of any event or penalty described above may inhibit our ability to commercialize our products and generate revenues.

We have only limited experience in regulatory affairs and intend to rely on consultants and other third parties for regulatory matters, which may affect our ability or the time we require to obtain necessary regulatory approvals.

We have limited experience in preparing and filing the applications necessary to gain regulatory approvals for our products and product candidates to the extent that we decide to make such applications ourselves. Moreover, the products that are likely to result from our development programs are based on new technologies that have not been extensively used in humans. The regulatory requirements governing these types of products may be less well defined or more rigorous than for conventional products. As a result, we may experience a longer regulatory review process in connection with obtaining regulatory approvals, if any, of products that we develop. We intend to rely on independent consultants for regulatory services and compliance and product development and filings in Europe, the United States and elsewhere. Any failure by our consultants to properly advise us regarding, or properly perform tasks related to, regulatory submission and other requirements could compromise our ability to develop and obtain regulatory approval of our products.

We and our strategic partners are subject to stringent regulation and any adverse regulatory action may materially adversely affect our financial condition and business operations.

Our and our strategic partners' products, development activities, and manufacturing processes are subject to extensive and rigorous regulation by numerous government agencies, including European regulatory authorities, the FDA, and other regulatory authorities. To varying degrees, each of these agencies monitors and enforces our compliance with laws and regulations governing the development, testing, manufacturing, labeling, marketing, and distribution of our products. The process of obtaining marketing approval or clearance in Europe, the United States, and other countries for new products or enhancements or modifications to existing products could:

- take a significant amount of time;
- require the expenditure of substantial resources;
- involve rigorous and expensive preclinical and clinical testing, as well as increased post-market surveillance;
- involve modifications, repairs, or replacements of our products; and
- result in limitations on the indicated uses of our products.

We cannot be certain that we, or our strategic partners, will receive required approval or clearance from European regulatory authorities, the FDA, or other regulatory authorities for new products or modifications to existing products on a timely basis. The failure to receive approval or clearance for significant new products or modifications to existing products on a timely basis could have a material adverse effect on our financial condition and results of operations.

Both before and after a product is commercially released, we and our strategic partners have ongoing responsibilities under FDA regulations. For example, we are required to comply with the FDA's Quality System Regulation, or QSR, which are the good manufacturing requirements that the FDA applies to medical devices, and which mandate that manufacturers adhere to certain requirements pertaining to, among other things, development of our products, validation of manufacturing processes, controls for purchasing product components, and documentation practices. As another example, FDA regulations require us to provide information to the FDA whenever there is evidence that reasonably suggests that a product may have caused or contributed to a death or serious injury, or that a malfunction occurred which would be likely to cause or contribute to a death or serious injury upon recurrence. Compliance with applicable regulatory requirements is subject to continual review and is monitored rigorously through, among other things, periodic inspections by the FDA, which may result in observations on Form 483 that require corrective action, and in some cases warning letters, and potentially stopping the manufacturing until issues are remedied. If the FDA were to conclude that we are not in compliance with applicable laws or regulations, or that any of our products are ineffective or pose an unreasonable health risk, the Company may withdraw or recall the product or the FDA could ban such products, detain or seize such products, order a recall, repair, replacement, or refund of such products, or require us to notify health professionals and others that the devices present unreasonable risks of substantial harm to the public health.

The FDA has been increasing its scrutiny of the medical device, drugs, and biologics industries, and regulatory agencies are expected to continue to scrutinize the industry closely with inspections, with possible enforcement actions by the FDA or other agencies. Additionally, the FDA may restrict manufacturing and impose other operating restrictions, enjoin and restrain certain violations of applicable law pertaining to medical products, and assess civil or criminal penalties against our officers, employees, or us. The FDA may also recommend prosecution to the Department of Justice. Any adverse regulatory action, depending on its magnitude, may restrict us from effectively manufacturing, marketing, and selling our products. In addition, negative publicity and product liability claims resulting from any adverse regulatory action could have a material adverse effect on our financial condition and results of operations.

Finally, the FDA issued regulations regarding "Current Good Manufacturing Practice Requirements for Combination Products" on January 22, 2013. These regulations may apply to some of our products if they are designated by the FDA as combination products, which are products composed of two or more regulated components, such as a drug and a medical device. There have been and will be additional costs associated with compliance with the FDA Good Manufacturing Practice Requirements regulations for Combination Products.

Governmental regulations have become increasingly stringent and more common, and we may become subject to even more rigorous regulation by governmental authorities in various countries in the future. Penalties for a company's non-compliance with governmental regulation could be severe, including revocation or suspension of a company's business license and criminal sanctions.

The impact of healthcare reform and other changes in the healthcare industry and in healthcare spending is currently unknown, and may adversely affect our business model.

The commercial potential for our approved products, if any, could be affected by changes in healthcare spending and policy in Europe, in the United States, and in other countries. We operate in a highly regulated industry and new laws, regulations, or judicial decisions, or new interpretations of existing laws, regulations, or decisions, related to healthcare availability, the method of delivery, or payment for healthcare products and services could negatively impact our business, operations, and financial condition.

In addition to the level of commercial success of our products, our future prospects are also dependent on our ability to successfully develop a pipeline of additional products, and we may not be successful in our efforts in using our platform technologies to identify or discover additional products.

The success of our business depends primarily upon our ability to identify, develop, and commercialize products based on our platform technology. Our research programs may fail to identify other potential products for clinical development for a number of reasons. Our research methodology may be unsuccessful in identifying potential products or our potential products may be shown to have harmful side effects or may have other characteristics that may make the products unmarketable or unlikely to receive marketing approval.

If any of these events occur, we may be forced to abandon our development efforts for a program or programs. Research programs to identify new products require substantial technical, financial, and human resources. We may focus our efforts and resources on potential programs or products that ultimately prove to be unsuccessful.

Risks Related to Our Reliance on Third Parties

We may not be successful in establishing and maintaining strategic partnerships, which could adversely affect our ability to develop and commercialize rhCollagen based products in 3D bioprinting and medical aesthetics and future products for medical and aesthetics markets.

To successfully develop and commercialize our products and product candidates, we will need substantial financial resources as well as expertise and physical resources and systems. We may elect to develop some or all of these physical resources and systems and expertise ourselves, or we may seek to collaborate with another company that can provide some or all of such physical resources and systems as well as financial resources and expertise. For example, in February 2021, we entered into the AbbVie Development Agreement pursuant to which we and AbbVie agreed to collaborate in the development and commercialization of dermal and soft tissue filler products for the medical aesthetics market, using our rhCollagen technology in combination with AbbVie's technology. AbbVie is collecting data and conducting a review of interim results from the first cohort of patients enrolled in the dermal and soft tissue filler clinical trials initiated in 2023 and next steps for the program are to be determined by AbbVie upon concluding their assessment.

We face significant competition in seeking appropriate partners for our products and product candidates, and the negotiation process is time-consuming and complex. In order for us to successfully partner our products and product candidates, potential partners must view our products and product candidates as economically valuable in markets they determine to be attractive in light of the terms that we are seeking and other available products for licensing by other companies. Even if we are successful in our efforts to establish strategic partnerships, the terms that we agree upon may not be favorable to us, and we may not be able to maintain such strategic partnerships if, for example, development or approval of a product is delayed or sales of an approved product are disappointing. Any delay in entering into strategic partnership agreements related to our products could delay the development and commercialization of our products and reduce their competitiveness even if they reach the market. If we fail to establish and maintain strategic partnerships related to our products, we will bear all of the risk and costs related to the development and commercialization of our products, and we will need to seek additional financing, hire additional employees and otherwise develop expertise which we do not have and for which we have not budgeted.

The risks in a strategic partnership include the following:

- the strategic partner may not apply the expected financial resources, efforts, or required expertise in developing the physical resources and systems necessary to successfully develop and commercialize a product or product candidate;
- the strategic partner may not invest in the development of a sales and marketing force and the related infrastructure at levels that ensure that sales of the products reach their full potential;
- we may be required to undertake the expenditure of substantial operational, financial, and management resources;

- we may be required to issue equity securities that would dilute our existing shareholders' percentage ownership;
- we may be required to assume substantial actual or contingent liabilities;
- we, or our strategic partner, may not receive requisite regulatory approvals;
- strategic partners could decide to withdraw a development program, or move forward with a competing product developed either independently or in collaboration with others, including our competitors;
- disputes may arise between us and a strategic partner that delay the development or commercialization or adversely affect the sales or profitability of the product; or
- the strategic partner may independently develop, or develop with third parties, products that could compete with our products.

In addition, a strategic partner for one or more of our products or product candidates may have the right to terminate the collaboration at its discretion. For example, AbbVie may terminate the AbbVie Development Agreement upon 60 days' written notice to us for any or no reason. Any early termination in a manner adverse to us could have a material adverse effect on our liquidity, financial condition and results of operations. Any termination may require us to seek a new strategic partner, which we may not be able to do on a timely basis, if at all, or require us to delay or scale back our development and commercialization efforts. The occurrence of any of these events could adversely affect the development and commercialization of our products or product candidates and materially harm our business and stock price by delaying the development of our products, and the sale of any products that may be approved by the FDA or other regulatory agencies, by slowing the growth of such sales, by reducing the profitability of the product and/or by adversely affecting the reputation of the product.

Further, in case of a breach of an agreement with us by a strategic partner, or upon termination by either party to the agreement for any reason, we may not be able to adequately protect our rights under these agreements, including intellectual property rights, or maintain exclusive rights to shared intellectual property rights. Furthermore, a strategic partner will likely negotiate for certain rights to control decisions regarding the development and commercialization of our products, if approved, and may not conduct those activities in the same manner as we would do so.

We may be dependent upon third-party collaborators, distributors, and resellers for a significant portion of our sales.

We depend upon sales through independent collaborators, distributors and resellers. While we are highly dependent upon acceptance of our products and solutions by such third parties and their active marketing and sales efforts relating to our products, most of our distributors and resellers may not be obligated to deal with us exclusively and are not contractually subject to minimum purchase requirements. In addition, some of our distributors and resellers may sell competing products or solutions. As a result, our distributors and resellers may give higher priority to products or services of our competitors, thereby reducing their efforts in selling our products and services.

There can be no assurance that such distributors and resellers will act as effective sales agents for us, that they will remain our partners, or that, if we terminate or lose any of them, we will be successful in replacing them. Any disruption in our distribution channels could adversely affect our business, operating results, and financial condition.

We expect to rely on third parties to conduct some aspects of our product manufacturing, protocol development, research, and preclinical and clinical testing, and these third parties may not perform satisfactorily.

We do not expect to independently conduct all aspects of our product manufacturing, protocol development, research, and preclinical and clinical testing. We currently rely, and expect to continue to rely, on third parties, including strategic partners, with respect to parts of these items.

Any of these third parties may terminate their engagements with us at any time or upon advance notice. If we need to enter into alternative arrangements, it could delay our product development activities. Our reliance on these third parties for research and development activities will reduce our control over these activities but will not relieve us of our responsibility to ensure compliance with all required regulations and study protocols.

If these third parties do not successfully carry out their contractual duties, meet expected deadlines, or conduct our studies in accordance with regulatory requirements or our stated study plans and protocols, we may not be able to complete, or may be delayed in completing, the preclinical studies and clinical trials required to support future FDA, European, or other approvals of our products.

Reliance on third-party manufacturers entails risks to which we would not be subject if we manufactured the products ourselves, including:

- the inability to negotiate manufacturing agreements with third parties under commercially reasonable terms;
- reduced control as a result of using third-party manufacturers for all aspects of manufacturing activities;
- termination or non-renewal of manufacturing agreements with third parties in a manner or at a time that is costly or damaging to us; and
- disruptions to the operations of our third-party manufacturers or suppliers caused by conditions unrelated to our business or operations, including the bankruptcy of the manufacturer or supplier.

Any of these events could lead to clinical trial delays or failure to obtain regulatory approval, or impact our ability to successfully commercialize future products. Some of these events could be the basis of action from European regulatory authorities, the FDA, or other regulatory authorities, including injunction, recall, seizure, or total or partial suspension of production.

We are relying on third parties to conduct, supervise, and monitor our existing pre-clinical studies, and our future clinical trials, and if these third parties perform in an unsatisfactory manner, it may harm our business.

We rely on our CROs and other consultants and third parties to conduct, supervise, and monitor our pre-clinical studies. In addition, as part of our future clinical trials, we expect to rely heavily on hospitals, clinic centers, and other institutions and third parties, including the principal investigators and their staff, to carry out our future clinical trials in accordance with our clinical protocols and designs. As part of our future clinical trials, we also expect to rely on a number of CROs to assist in undertaking, managing, monitoring, and executing future clinical trials as well as clinical data management organizations, medical institutions, and clinical investigators to conduct our development efforts in the future. We compete with many other companies for the resources of these third parties, and large pharmaceutical and medical device companies often have significantly more extensive agreements and relationships with such third-party providers, and such third-party providers may prioritize the requirements of such large pharmaceutical and medical device companies over ours. The third parties on whom we rely on may terminate their engagements with us at any time, which may cause delay in the development and commercialization of our products or product candidates. If any such third party terminates its engagement with us or fails to perform as agreed, we may be required to enter into alternative arrangements, which would result in significant cost and delay to our product development program. Moreover, our agreements with such third parties generally do not provide assurances regarding employee turnover and availability, which may cause interruptions in the research on our products by such third parties.

Moreover, while our reliance on these third parties for certain development, trial and management activities will reduce our control over these activities, it will not relieve us of our responsibilities. For example, European regulatory authorities, the FDA, and other regulatory authorities require compliance with regulations and standards, including GCP requirements, for designing, conducting, monitoring, recording, analyzing, and reporting the results of clinical trials to ensure that the data and results from trials are credible and accurate and that the rights, integrity, and confidentiality of trial participants are protected. Although we expect to rely on third parties to conduct our clinical trials, we are responsible for ensuring that each of these clinical trials is conducted in accordance with its general investigational plan and protocol under legal and regulatory requirements. Regulatory authorities enforce these GCP requirements through periodic inspections of trial sponsors, principal investigators, and trial sites. If we or any of our CROs or these other third parties fail to comply with applicable GCP requirements, the clinical data generated in our clinical trials may be deemed unreliable, and European regulatory authorities, the FDA, or other regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP requirements.

If CROs and other third parties do not successfully carry out their duties under their agreements with us, if the quality or accuracy of the data they obtain is compromised due to their failure to adhere to trial protocols or to regulatory requirements, or if they otherwise fail to comply with regulations and trial protocols or meet expected standards or deadlines, the trials of our products or product candidates may not meet regulatory requirements. If trials do not meet regulatory requirements or if these third parties need to be replaced, the development of our products or product candidates may be delayed, suspended, or terminated, or the results may not be acceptable. If any of these events occur, we may not be able to obtain regulatory approval of our products on a timely basis, at a reasonable cost, or at all.

Our reliance on third parties may require us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed.

Because we rely on third parties to manufacture our products, and because we collaborate with various organizations and academic institutions on the advancement of our technology, we must, at times, share trade secrets with them. We seek to protect our proprietary technology, rights and information in part by entering into confidentiality agreements and, if applicable, material transfer agreements, collaborative research agreements, consulting agreements, or other similar agreements with our strategic partners, service providers, advisors, employees, and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, such as proprietary information and trade secrets. Despite these contractual provisions, the need to share trade secrets and other confidential information increases the risk that such trade secrets and information become known by potential competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know-how and trade secrets, discovery by a third party of our trade secrets or other unauthorized use or disclosure would impair our intellectual property rights and protections in our products.

In addition, these agreements typically restrict the ability of our collaborators, advisors, employees, and consultants to publish data potentially relating to our trade secrets. Our academic collaborators typically have rights to publish data, provided that we are notified in advance and may delay publication for a specified time in order to secure our intellectual property rights arising from the collaboration. In other cases, publication rights are controlled exclusively by us, although in some cases we may share these rights with other parties. Despite our efforts to protect our trade secrets, our competitors may discover our trade secrets, either through breach of these agreements, independent development, or publication of information including our trade secrets in cases where we do not have proprietary or otherwise protected rights at the time of publication.

It could be difficult to replace some of our suppliers and equipment vendors.

Outside vendors provide key components, raw materials, and equipment used in the manufacture of our products. An uncorrected defect or supplier's variation in a component or raw material, either unknown to us or incompatible with our manufacturing process, could harm our ability to manufacture products or conduct research and developments activities. We may not be able to find a sufficient alternative supplier in a reasonable time period, or on commercially reasonable terms, if at all, and our ability to conduct research and development activities or produce and supply our products could be impaired.

If we were suddenly unable to purchase from one or more of these companies, we would need a significant period of time to qualify a replacement, and the production of any affected products could be disrupted. While it is our policy to maintain sufficient inventory of components so that our development programs and production will not be significantly disrupted even if a particular component or material is not available for a period of time, we remain at risk that we will not be able to qualify new components or materials quickly enough to prevent a disruption if one or more of our suppliers ceases production of important components or materials, or if we are unable to quickly procure replacement equipment.

Risks Related to Our Business Operations

Our future success depends on our ability to retain senior management, consultants, and advisors and to attract, retain, and motivate qualified personnel.

We are dependent on principal members of our executive team listed under "Management" in this Annual Report, the loss of whose services may adversely impact the achievement of our objectives. While we have entered into employment agreements with each member of our senior management, any of them could leave our employment at any time, subject to advance notice periods. Recruiting and retaining other qualified employees, consultants, and advisors for our business, including scientific and technical personnel, will also be critical to our success. There is currently a shortage of skilled executives in our industry, which is likely to continue. As a result, competition for skilled personnel is intense and the turnover rate can be high. We may not be able to attract and retain personnel on acceptable terms given the competition among numerous pharmaceutical and medical device companies for individuals with similar skill sets. In addition, failure to succeed in clinical trials may make it more challenging to recruit and retain qualified personnel. The inability to recruit or loss of the services of any executive, key employee, consultant, or advisor may impede the progress of our research, development, and commercialization objectives.

Our collaborations with outside scientists and consultants may be subject to restriction and change.

We work with medical experts, chemists, biologists, and other scientists at academic and other institutions, and consultants who assist us in our research, development, and regulatory efforts, including the members of our scientific advisory board. In addition, these scientists and consultants have provided, and we expect that they will continue to provide, valuable advice regarding our programs and regulatory approval processes. These scientists and consultants are not our employees and may have other commitments that would limit their future availability to us. If a conflict of interest arises between their work for us and their work for another entity, we may lose their services. In addition, we are limited in our ability to prevent them from establishing competing businesses or developing competing products. For example, if a key scientist acting as a principal investigator in any of our clinical trials identifies a potential product that is more scientifically interesting to his or her professional interests, his or her availability to remain involved in our clinical trials could be restricted or eliminated.

Our business and operations would suffer in the event of computer system failures or security breaches.

Despite the implementation of security measures, our internal computer systems, and those of our strategic partners, CROs and other third parties on which we rely, are vulnerable to damage from computer viruses, unauthorized access, cyber-attacks, natural disasters, fire, terrorism, war, and telecommunication and electrical failures. If such an event were to occur and interrupt our operations, it could result in a material disruption of our development programs. For example, the loss of clinical trial data from ongoing or planned clinical trials could result in delays in our or our strategic partners' regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach results in a loss of or damage to our data or applications, loss of trade secrets or inappropriate disclosure of confidential or proprietary information, including protected health information or personal data of employees or former employees, access to our clinical data, or disruption of the manufacturing process, we could incur liability and the further development of our product candidates could be delayed. We may also be vulnerable to cyber-attacks by hackers or other malfeasance. This type of breach of our cybersecurity may compromise our confidential information and/or our financial information and adversely affect our business or result in legal proceedings. Further, these cybersecurity breaches may inflict reputational harm upon us that may result in decreased market value and erode public trust.

We may in the future need to expand our organization and we may experience difficulties in managing this growth, which could disrupt our operations.

As of March 15, 2025, we had 57 employees. While we recently undertook certain cost cutting measures including reducing our workforce however, as we mature and undertake the activities required to advance our products and product candidates, we may expand our full-time employee base and to hire more consultants and contractors. Our management may need to divert a disproportionate amount of its attention away from our day-to-day activities and devote a substantial amount of time to managing these growth activities. We may not be able to effectively manage the expansion of our operations, which may result in weaknesses in our infrastructure, operational setbacks, loss of business opportunities, loss of employees, and reduced productivity among remaining employees. Our expected growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of additional products. If our management is unable to effectively manage our growth, our expenses may increase more than expected, our ability to generate or grow revenue could be compromised, and we may not be able to implement our business strategy. Our future financial performance and our ability to commercialize products and compete effectively will depend, in part, on our ability to effectively manage any future growth.

Our employees, principal investigators, consultants, and commercial partners may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements and insider trading.

We are exposed to the risk of fraud or other misconduct by our employees, principal investigators, consultants, commercial and strategic partners and other third parties. Misconduct by these parties could include intentional failures to comply with regulations, provide accurate information to European regulatory authorities, the FDA and other regulatory authorities, comply with healthcare fraud and abuse laws and regulations, report financial information or data accurately, or disclose unauthorized activities to us. In particular, sales, marketing, and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing, and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs, and other business arrangements. Such misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and cause serious harm to our reputation. We have adopted a code of business conduct and ethics applicable to all of our employees, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions.

We face potential product liability, and, if successful claims are brought against us, we may incur substantial liability and costs. If the use of our products harm patients, or is perceived to harm patients even when such harm is unrelated to our products, our regulatory approvals could be revoked or otherwise negatively impacted and we could be subject to costly and damaging product liability claims.

The use of our products in clinical trials and the sale of any products exposes us to the risk of product liability claims. Product liability claims might be brought against us by consumers, healthcare providers, pharmaceutical and medical device companies, or others that sell or otherwise come into contact with our products. There is a risk that our products may induce adverse events. If we cannot successfully defend against product liability claims, we could incur substantial liability and costs. In addition, regardless of merit or eventual outcome, product liability claims may result in:

- impairment of our business reputation;
- withdrawal of clinical trial participants;
- costs due to related litigation;
- distraction of management’s attention from our primary business;
- substantial monetary awards to patients or other claimants;
- the inability to commercialize our products;

- decreased demand for our products, if approved for commercial sale; and
- impairment of our ability to obtain product liability insurance coverage.

We currently carry product liability insurance of $5.0 million for sales of VergenixFG and VergenixSTR. If we obtain marketing approval for additional products, we intend to obtain insurance coverage to include the sale of those commercial products, but we may not be able to obtain product liability insurance on commercially reasonable terms or in adequate amounts. On occasion, large judgments have been awarded in class action lawsuits based on medical treatments that had unanticipated adverse effects. A product liability claim or series of claims brought against us could cause our ordinary share price to decline and, if judgments exceed our insurance coverage, could materially and adversely affect our financial position.

Our development and production of rhCollagen relies upon the continued availability of tobacco plants, and any interruption in availability or supply of tobacco plants may delay production and adversely affect commercial utilization of our rhCollagen-based products.

Our products are all based on our rhCollagen extracted from tobacco plants. Any disruption to the supply of tobacco plants or any change in its availability for use would delay our production of collagen and adversely affect commercial utilization of our products. The occurrence of severe adverse weather conditions, soil salination or crop diseases may have a potentially devastating impact upon our tobacco production. The effect of severe adverse weather conditions or the occurrence and effect of crop disease may reduce yields in our plants or require higher levels of investment to maintain yields, even when only a portion of the crop is damaged. We cannot assure you that severe future adverse weather conditions, crop diseases or any other interruption in availability or supply of tobacco plants will not adversely impact our operating results and financial condition.

If our existing rhCollagen production sites or any new facilities are damaged or destroyed, or production at these facilities is otherwise interrupted, our business and prospects would be negatively affected.

We currently have two production sites in Israel where we manufacture rhCollagen. During 2024, we had a mechanical failure at our Yessod Hama'ala facility that occurred during the production process resulting in the temporary shutdown of our manufacturing operations. In addition, during 2024, we took precautionary measures to close our facility in Yessod Hama'ala for an extended period, although it is now operational, due to the war and its proximity to the border with Lebanon. See "—Risks Related to Our Operations in Israel — Potential political, economic, and military instability in the State of Israel, where the majority of our senior management and our research and development facilities are located, may adversely impact our results of operations."

If our existing production facilities or any new facility, or the equipment in it, are damaged or destroyed, we likely would not be able to quickly or inexpensively replace our production capacity. Any new facility needed to replace our existing production facility would need to comply with the necessary regulatory requirements and be tailored to our production requirements and processes. We would need regulatory approval before using any products manufactured at a new facility in clinical trials or selling any products that are ultimately approved. Such an event could delay our or our strategic partners' clinical trials or, if any of our products are approved by the regulator, reduce or eliminate our product sales.

If we fail to comply with environmental, health, and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse impact on the success of our business.

We are subject to numerous environmental, health, and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment, and disposal of hazardous materials and wastes. These laws, regulations, and permits could potentially require the expenditure by us of significant amounts for compliance or remediation. If we fail to comply with such laws, regulations, or permits, we may be subject to fines and other civil, administrative, or criminal sanctions, including the revocation of permits and licenses necessary to continue our business activities. See "Item 4.B. Environmental, Health, and Safety Matters" for additional information.

Our operations involve the use of hazardous materials, including chemicals and biological materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties.

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials or other work-related injuries, this insurance may not provide adequate coverage against potential liabilities. In addition, we may incur substantial costs in order to comply with current or future environmental, health, and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties, or other sanctions.

We may use our financial and human resources to pursue a particular research program or product and fail to capitalize on programs or products that may be more profitable or for which there is a greater likelihood of success.

Because we have limited resources, we may forego or delay pursuit of opportunities with certain programs or products or for indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs for products may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product, we may relinquish valuable rights to that product through strategic collaboration, licensing, or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product, or we may allocate internal resources to a product in a therapeutic area in which it would have been more advantageous to enter into a collaboration arrangement.

We are subject to foreign currency exchange risk, and fluctuations between the U.S. dollar and the NIS, the Euro, and other non-U.S. currencies may adversely affect our earnings and results of operations.

We currently operate in two different currencies. While the U.S. dollar is our functional and reporting currency, we incur a portion of our expenses in NIS. As a result, our financial results may be adversely affected by fluctuations in currency exchange rates.

We are exposed to the risks that the NIS may appreciate relative to the U.S. dollar, in such event, the dollar-denominated results of operations would be adversely affected. We cannot predict any future trends in the rate of inflation in Israel or the rate of devaluation (if any) of the NIS against the dollar. For example, the average exchange rate of the dollar against the NIS decreased in 2021, but increased in 2022 through 2024. Market volatility and currency fluctuations may limit our ability to cost-effectively hedge against our foreign currency exposure. Hedging strategies may not eliminate our exposure to foreign exchange rate fluctuations and may involve costs and risks of their own, such as devotion of management time, external costs to implement the strategies, and potential accounting implications. Foreign currency fluctuations, independent of the performance of our underlying business, could lead to materially adverse results or could lead to positive results that are not repeated in future periods.

We or the third parties upon whom we depend may be adversely affected by natural disasters and/or health epidemics, and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

Natural disasters could severely disrupt our operations and have a material adverse effect on our business, results of operations, financial condition and prospects. If a natural disaster, power outage, health epidemic or other event occurred that prevented us from using all or a significant portion of our office, manufacturing and/or lab spaces, that damaged critical infrastructure, such as the manufacturing facilities of our third-party contract manufacturers, CROs, clinical sites, tobacco plants growers, third parties ongoing activities and schedules or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible for us to continue our plans and business for a substantial period of time. The disaster recovery and business continuity plans we have in place may prove inadequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which could have a material adverse effect on our business.

Our business may be adversely affected if there is a resurgence of the COVID-19 pandemic.

Public health epidemics or outbreaks could adversely impact our business. For example, in late 2019, a COVID-19 pandemic broke out across the globe, including in Israel and the United States. Many countries around the world, including in Israel and the United States, implemented significant governmental measures to control the spread of the virus, including temporary closure of businesses, severe restrictions on travel and the movement of people, and other material limitations on the conduct of business. In response, for several months in 2020, we implemented remote working and workplace protocols for our employees in accordance Israeli Ministry of Health requirements to ensure employee safety and all employees have been instructed on and encouraged to practice best social distancing behaviors. If there is a resurgence of COVID-19 its spread may materially affect us economically. While the potential economic impact brought by, and the duration of, any future resurgence of the COVID-19 pandemic may be difficult to assess or predict, it has already caused, and could result in further, significant disruption of global financial markets, reducing our ability to access capital, which could in the future negatively affect our liquidity and financial position. In addition, the trading prices for other companies have been highly volatile as a result of the COVID-19 pandemic. As a result, we may face difficulties raising capital through sales of our ordinary shares or other securities and such sales may be on unfavorable terms. To the extent that future waves of COVID-19 disrupt normal business operations, we may face operational challenges with our services, and we likely will have to adopt remote working and workplace protocols for employees in accordance with government requirements and other measures to minimize such impact.

Our business, operating results and growth rates may be adversely affected by current or future unfavorable economic and market conditions and adverse developments with respect to financial institutions and associated liquidity risk.

Our business depends on the economic health of the global economies. If the conditions in the global economies remain uncertain or continue to be volatile, or if they deteriorate, including as a result of the impact of military conflict, such as the war between Russia and Ukraine and Hamas and Israel, terrorism or other geopolitical events, our business, operating results and financial condition may be materially adversely affected. Economic weakness, inflation and increases in interest rates, limited availability of credit, liquidity shortages and constrained capital spending have at times in the past resulted, and may in the future result, in challenging and delayed sales cycles, slower adoption of new technologies and increased price competition, and could negatively affect our ability to forecast future periods, which could result in an inability to satisfy demand for our products and a loss of market share.

In addition, increases in inflation raise our costs for commodities, labor, materials and services and other costs required to grow and operate our business, and failure to secure these on reasonable terms may adversely impact our financial condition. Additionally, increases in inflation, along with the uncertainties surrounding geopolitical developments and global supply chain disruptions, have caused, and may in the future cause, global economic uncertainty and uncertainty about the interest rate environment, which may make it more difficult, costly or dilutive for us to secure additional financing. A failure to adequately respond to these risks could have a material adverse impact on our financial condition, results of operations or cash flows.

There can be no assurance that future credit and financial market instability and a deterioration in confidence in economic conditions will not occur. Our general business strategy may be adversely affected by any such economic downturn, liquidity shortages, volatile business environment or continued unpredictable and unstable market conditions. If the current equity and credit markets deteriorate, or if adverse developments are experienced by financial institutions, it may cause short-term liquidity risk and also make any necessary debt or equity financing more difficult, more costly, more onerous with respect to financial and operating covenants and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and stock price and could require us to alter our operating plans. In addition, there is a risk that one or more of our service providers, financial institutions, manufacturers, suppliers and other partners may be adversely affected by the foregoing risks, which could directly affect our ability to attain our operating goals on schedule and on budget.

Environmental, social and corporate governance (ESG) issues, including those related to climate change and sustainability, may have an adverse effect on our business, financial condition and results of operations and damage our reputation.

There is growing attention from certain investors, customers, consumers, employees and other stakeholders concerning ESG matters. Additionally, public interest and legislative pressure related to public companies' ESG practices continue to grow. If our ESG practices fail to meet regulatory requirements or investor, customer, consumer, employee or other shareholders' evolving expectations and standards for responsible corporate citizenship in areas including environmental stewardship, support for local communities, board of directors and employee diversity, human capital management, employee health and safety practices, product quality, supply chain management, corporate governance and transparency, our reputation, brand and employee retention may be negatively impacted, and our customers and suppliers may be unwilling to continue to do business with us.

Customers, consumers, investors and other shareholders are increasingly focusing on environmental issues, including climate change, energy and water use, plastic waste and other sustainability concerns. Concern over climate change may result in new or increased legal and regulatory requirements to reduce or mitigate impacts to the environment. Changing customer and consumer preferences or increased regulatory requirements may result in increased demands or requirements regarding plastics and packaging materials, including single-use and non-recyclable plastic products and packaging, other components of our products and their environmental impact on sustainability, or increased customer and consumer concerns or perceptions (whether accurate or inaccurate) regarding the effects of substances present in certain of our products. Complying with these demands or requirements could cause us to incur additional manufacturing, operating or product development costs.

If we do not adapt to or comply with new regulations, which may require us to incur significant additional costs to comply and impose increased oversight obligations on our management and board of directors, or fail to meet evolving investor, industry or stakeholder expectations and concerns regarding ESG issues, investors may reconsider their capital investment in our company, we may become subject to penalties, and customers and consumers may choose to stop purchasing our products, if approved for commercialization, which could have a material adverse effect on our reputation, business or financial condition.

Risks Related to Our Intellectual Property

We have an extensive worldwide patent portfolio. The cost of maintaining our worldwide patent protection is high and requires continuous review and compliance with procedural and documentary requirements. We may not be able to effectively maintain our intellectual property position throughout the major markets of the world.

The U.S. Patent and Trademark Office, or U.S. PTO, and foreign patent authorities require maintenance fees and payments as well as continued compliance with several procedural and documentary requirements. Non-compliance may result in abandonment or lapse of the subject patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance may result in reduced royalty payments for lack of patent coverage in a particular jurisdiction from our collaboration partners or may result in competition, either of which could have a material adverse effect on our business.

We have made, and will continue to make, certain strategic decisions in balancing costs and the potential protection afforded by the patent laws of certain countries. As a result, we may not be able to prevent third parties from practicing our inventions in all countries throughout the world, or from selling or importing products made using our inventions in and into the United States or other countries. Third parties may use our technologies in territories in which we have not obtained patent protection to develop their own products and, further, may infringe our patents in territories which provide inadequate enforcement mechanisms, even if we have patent protection. Such third-party products may compete with our products, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

If we are unable to obtain or protect intellectual property rights related to our products and product candidates, we may not be able to obtain exclusivity for our products or prevent others from developing similar competitive products.

We rely upon a combination of granted patents, pending patent applications, trade secret protection, and confidentiality agreements to protect the intellectual property related to our products and product candidates. The strength of patents in the field of regenerative medicine involves complex legal and scientific questions and can be uncertain. The patent applications that we own may fail to result in issued patents with claims that cover our products in the United States or in other countries. There is no assurance that all of the potentially relevant prior art relating to our patents and patent applications has been found, which can invalidate a patent or prevent a patent from issuing from a pending patent application. Even if patents do successfully issue and even if such patents cover our products, third parties may challenge their validity, enforceability, or scope, which may result in the patent claims being narrowed or invalidated. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property, provide exclusivity for our products, or prevent others from designing around our claims. Any of these outcomes could impair our ability to prevent competition from third parties.

Our ability to attract third parties to collaborate with us to develop products and our ability to commercialize future products may be adversely affected if the patent applications we hold with respect to our techniques or products fail to issue, if the breadth or strength of our patent protection is threatened, or if our patent portfolio fails to provide meaningful exclusivity for our products. Third parties may challenge their validity or enforceability of our patents or patents that issue in the future from our patent applications, which may result in such patents being narrowed, invalidated, or held unenforceable. Even if our patents and patent applications are not challenged by third parties, they may not prevent others from designing around our claims and may not otherwise adequately protect our products. If the breadth or strength of protection provided by the patents and patent applications we hold with respect to our products is threatened, our ability to commercialize our products may be adversely affected.

Discoveries are generally published in the scientific literature well after their actual development, and patent applications in the United States and other countries are typically not published until 18 months after filing and in some cases are never published. Therefore, we cannot be certain that we were the first to make the inventions claimed in our owned granted patents or patent applications, or that we were the first to file for patent protection covering such inventions. Subject to meeting other requirements for patentability, for United States patent applications filed prior to March 16, 2013, the first to invent the claimed invention is entitled to receive patent protection for that invention while, outside the United States, the first to file a patent application encompassing the invention is entitled to patent protection for the invention. In addition, patents have a limited lifespan. In the United States, the expiration of a patent is generally 20 years from the earliest non-provisional filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Once the patent life has expired for a product, we may be open to competition from third party products, including products that are copies of our products. This risk is material in light of the length of the development process of our products and lifespan of our current patent portfolio.

In addition to the protection afforded by patents, we rely on trade secret protection and confidentiality agreements to protect our proprietary know-how and other proprietary information that is not patentable or that we elect not to patent. For example, many of our discovery, development, and manufacturing processes involve proprietary know-how, information, or technology that is not covered by patents. We seek to protect our trade secrets and proprietary technology and processes, in part, by entering into confidentiality agreements with our employees, consultants, scientific advisors, and contractors. We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. Security measures may be breached, and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. Although we contractually require all of our employees and consultants to assign their inventions to us, and all of our employees, consultants, advisors, and any third parties who have access to our proprietary know-how, information, or technology to enter into confidentiality agreements, we cannot provide any assurances that all such agreements have been duly executed, that our trade secrets and other confidential proprietary information will not be disclosed, or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Misappropriation or unauthorized disclosure of our trade secrets could impair our competitive position and may have a material adverse effect on our business. Additionally, if the steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating the trade secret. In addition, others may independently discover our trade secrets and proprietary information. For example, the FDA, as part of its Transparency Initiative, is currently considering whether to make additional information publicly available on a routine basis, including information that we may consider to be trade secrets or other proprietary information, and it is not clear at the present time how the FDA's disclosure policies may change in the future, if at all.

Further, the laws of some countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and in other countries. If we are unable to prevent material disclosure of the non-patented intellectual property related to our technologies to third parties, and there is no guarantee that we will have any such enforceable trade secret protection, we may not be able to establish or maintain a competitive advantage in our market.

Third-party claims of intellectual property infringement may prevent or delay our development and commercialization efforts.

Our commercial success depends in part on our avoiding infringement of the patents and proprietary rights of third parties. There is a substantial amount of litigation, both within and outside the United States, involving patents and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, oppositions, and *inter partes* review proceedings before the U.S. PTO, and corresponding foreign patent offices. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are pursuing development technologies. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our products may be subject to claims of infringement of the patent rights of third parties.

Third parties may assert that we are employing their proprietary technology without authorization. There may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture, or methods for treatment related to the use or manufacture of our products. Because patent applications can take many years to issue, there may be currently pending patent applications which may later result in issued patents that our products may be accused of infringing. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of any of our products or any final product itself, the holders of any such patents may be able to block our ability to commercialize such product unless we obtained a license under the applicable patents, or until such patents expire. Similarly, if any third-party patents were held by a court of competent jurisdiction to cover aspects of our formulations, processes for manufacture, or methods of use, the holders of any such patents may be able to block our ability to develop and commercialize the applicable product unless we obtained a license or until such patent expires. In either case, such a license may not be available on commercially reasonable terms or at all.

The patent landscape in competitive product areas is highly complex and there may be patents of third parties of which we are unaware that may result in claims of infringement. Accordingly, there can be no assurance that our products do not infringe the proprietary rights of third parties. Parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our products. Defense of such claims, regardless of their merit, would involve substantial litigation expenses and would be a substantial diversion of financial and employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, pay royalties, redesign our infringing products, or obtain one or more licenses from third parties, which may be impossible or require substantial time and monetary expenditure.

We intend, if necessary, to vigorously enforce our intellectual property to protect the proprietary position of our products. Active efforts to enforce our patents may include litigation, post-grant patent challenges, administrative proceedings, or all of the foregoing, depending on the potential benefits that might be available from those actions and the costs associated with undertaking those efforts against third parties. We review and monitor publicly available information regarding products that may be competitive with our products and intend to assert our intellectual property rights where appropriate.

We may enter into license agreements with third parties, and if we fail to comply with our obligations in such agreements under which we license intellectual property rights from third parties or otherwise experience disruptions to our business relationships with our licensors, we could lose license rights that are important to our business.

We may need to obtain licenses from third parties to advance our research or allow commercialization of our products and product candidates. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we may be required to expend significant time and resources to develop or license replacement technology. If we are unable to do so, we may be unable to develop or commercialize the affected products.

We may be involved in lawsuits or administrative proceedings to obtain, protect or enforce our patents, which could be expensive, time consuming, and unsuccessful.

Competitors may infringe our patents. To counter infringement or unauthorized use, we may be required to file an infringement suit, which can be expensive and time consuming. In addition, in an infringement proceeding, the defendant may file a countersuit, challenging the validity or enforceability of our patent. In that case, a court may decide that a patent of ours is not valid, is unenforceable, or is not infringed, or it may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly and could put our patent applications at risk of not issuing.

We may not be able to prevent misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions, or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the trading price of our ordinary shares.

Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents.

On September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to U.S. patent law, including provisions that affect the way patent applications are prosecuted and also affect patent litigation. The U.S. PTO has developed regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first to file provisions which were enacted March 16, 2013. However, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. The Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. We may become involved in post-grant proceedings challenging our patents or the patents of others, and the outcome of any such proceedings is highly uncertain. An unfavorable outcome in any such proceedings could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology and compete directly with us, or result in our inability to manufacture, develop, or commercialize our products without infringing the patent rights of others.

We may be subject to claims that our employees, consultants, or independent contractors have wrongfully used or disclosed confidential information of third parties or, that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

Certain of our employees and personnel were previously employed at universities, medical institutions, or other biotechnology or pharmaceutical companies. Although we try to ensure that our employees, consultants, and independent contractors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or our employees, consultants, or independent contractors have inadvertently or otherwise used or disclosed intellectual property, including trade secrets or other proprietary information, of any of our employee's former employer or other third parties. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees. Furthermore, universities or medical institutions who employ some of our key employees and personnel in parallel to their engagement by us may claim that intellectual property developed by such person is owned by the respective academic or medical institution under the respective institution, intellectual property policy or applicable law.

We may become subject to claims for remuneration or royalties for assigned service invention rights by our employees, which could result in litigation and adversely affect our business.

A significant portion of our intellectual property has been developed by our employees in the course of their employment for us. Section 134 of the Israeli Patents Law, 5727-1967, or the Patents Law, grants employees the right to receive consideration for service inventions unless otherwise provided in an agreement between the parties. According to a decision by the special Committee for Compensations and Royalties formed under the Patents Law, or the Committee, an employee's right to receive consideration for service inventions is a personal right and is entirely separate from the proprietary rights in such invention. A decision in May 2014 by the Committee clarifies that the right to receive consideration under Section 134 can be waived and that such waiver does not necessarily have to be explicit. However, the Committee has the authority to examine, on a case by case basis, the general contractual framework between the parties, using interpretation rules of the general Israeli contract laws. Although such decision seems to alleviate the requirement to obtain an explicit waiver for royalties for service inventions under Section 134 of the Patents Law, to the extent that there is no explicit waiver in an employment agreement, the existence of such waiver will be subject to the interpretation of the Committee. Further, the Committee has not yet determined one specific formula for calculating this remuneration (but rather uses the criteria specified in the Patents Law) nor the criteria or circumstances under which an employee's waiver of his right to remuneration will be disregarded. We generally enter into assignment-of-invention agreements with our employees pursuant to which such individuals assign to us all rights to any inventions created in the scope of their employment or engagement with us. Although our employees have agreed to assign to us service invention rights, we may face claims demanding remuneration in consideration for assigned inventions. As a consequence of such claims, we could be required to pay additional remuneration or royalties to our current or former employees, or be forced to litigate such claims, which could negatively affect our business.

We may be subject to claims challenging the inventorship or ownership of our patents and other intellectual property.

We may be subject to claims that former employees, collaborators, or other third parties have an ownership interest in our patents or other intellectual property. Ownership disputes may arise in the future, for example, from conflicting obligations of consultants or others who are involved in developing our products. Litigation may be necessary to defend against these and other claims challenging inventorship or ownership. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

Obtaining and maintaining our patent protection requires compliance with various procedural, document submissions, fee payments, and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees, renewal fees, annuity fees, and various other governmental fees on patents and applications are and will be due to be paid to the U.S. PTO and various governmental patent agencies outside of the United States in several stages over the lifetime of the patents and applications. The U.S. PTO and various non-U.S. governmental patent agencies require compliance with a number of procedural, documentary, fee payment, and other similar provisions during the patent application process. There are situations in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction.

Issued patents covering our products or product candidates could be found invalid or unenforceable if challenged in court or in administrative proceedings.

If we initiate legal proceedings against a third party to enforce a patent covering one of our products or product candidates, the defendant may contend that the patent covering our product is invalid, unenforceable, or fails to cover the product or the infringing product. In patent litigation in the United States, defendants commonly allege that asserted patent claims are invalid and unenforceable. Grounds for a validity challenge could be an alleged failure to meet one or more of several statutory requirements, including lack of novelty, obviousness, lack of written description, indefiniteness, and non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the U.S. PTO, or made a misleading statement, during prosecution. Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, post grant review, and equivalent proceedings in foreign jurisdictions, such as opposition proceedings. Such proceedings could result in revocation, amendments to our patent claims, or statements being made on the record such that our claims may no longer be construed to cover our products. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity, unenforceability, or non-infringement, we would lose at least part, and perhaps all, of the patent protection on our products. For example, as further described below, in July 2017, Fibrogen, Inc., or Fibrogen, prevailed in an administrative challenge to one of our patents in Europe, resulting in the revocation of the patent and the abandonment of another patent. Even if resolved in our favor, litigation, or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses, and could distract our technical and management personnel from their normal responsibilities. Moreover, third parties may continue to initiate new proceedings in the United States and foreign jurisdictions to challenge our patents from time to time.

In addition, there could be public announcements of the results of hearings, motions, or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the market price of our ordinary shares. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing, or distribution activities.

Changes in U.S. patent law could diminish the value of patents in general, thereby impairing our ability to protect our products or product candidates.

As is the case with other companies in our industry, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biotechnology industry involve both technological and legal complexity, and therefore is costly, time consuming, and inherently uncertain. In addition, in recent years, the United States enacted and implemented wide-ranging patent reform legislation. Recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in some situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents that had already been granted. The patent laws and regulations may change in unpredictable ways through actions of the U.S. Congress, the federal courts, and the U.S. PTO, in the future, and any changes may adversely affect our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

We may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting, and defending patents on products in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Potential competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as in the United States. These products may compete with our products, if approved, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets, and other intellectual property protection, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Intellectual property rights do not address all potential threats to any competitive advantage we may have.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and intellectual property rights may not adequately protect our business or permit us to maintain our competitive advantage. The following examples are illustrative:

- Others may be able to make products that are the same as or similar to our current or future products but that are not covered by the claims of the patents that we own or have exclusively licensed.
- We or any of our licensors or strategic partners might not have been the first to make the inventions covered by the issued patent or pending patent application that we own or have exclusively licensed.
- We or any of our licensors or strategic partners might not have been the first to file patent applications covering certain of our inventions.
- Others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights.
- The prosecution of our pending patent applications may not result in granted patents.
- Granted patents that we own or have exclusively licensed may not provide us with any competitive advantages, or may be held invalid or unenforceable, as a result of legal challenges by our competitors.
- Patent protection on our products may expire before we are able to develop and commercialize the product, or before we are able to recover our investment in the product.
- Our competitors might conduct research and development activities in the United States and other countries that provide a safe harbor from patent infringement claims for such activities, as well as in countries in which we do not have patent rights, and may then use the information learned from such activities to develop competitive products for sale in markets where we intend to market our products.

Risks Related to the Ownership of our Ordinary Shares

The market price of our ordinary shares may be highly volatile.

The trading price of our ordinary shares has been, and is likely to continue to be, volatile. The following factors, some of which are beyond our control, in addition to other risk factors described in this Annual Report may have a significant impact on the market price of our ordinary shares:

- adverse results or delays in preclinical studies or clinical trials;
- reports of adverse events in other similar products or clinical trials of such products;
- inability to obtain additional funding;

- any delay in filing a regulatory submission for any of our products or product candidates and future products and any adverse development or perceived adverse development with respect to the FDA's review or European authorities' review of that regulatory submission;
- failure to develop successfully and commercialize our products or product candidates and future products;
- failure to enter into or maintain strategic collaborations;
- failure by us or strategic collaboration partners to prosecute, maintain, or enforce our intellectual property rights;
- changes in laws or regulations applicable to future products;
- inability to scale up our manufacturing capabilities, inability to obtain adequate supply for our products, or the inability to do so at acceptable prices;
- adverse regulatory decisions, including by the IIA under the Innovation Law;
- introduction of new products, services, or technologies by our competitors;
- failure to meet or exceed financial projections we may provide to the public;
- failure to meet or exceed the financial expectations of the investment community;
- the perception of the biotechnology industry by the public, legislatures, regulators, and the investment community;
- announcements of significant acquisitions, strategic partnerships, joint ventures, or capital commitments by us or our competitors;
- disputes or other developments relating to proprietary rights, including patents, litigation matters, and our ability to obtain patent protection for our technologies;
- additions or departures of key scientific or management personnel;
- significant lawsuits, including patent or shareholder litigation;
- changes in the market valuations of similar companies;
- sales of our ordinary shares by us or our shareholders in the future; and
- trading volumes of our ordinary shares.

In addition, companies trading in the stock market in general, and life science companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our ordinary shares, regardless of our actual operating performance. In the past, following periods of volatility in the market price of a company's securities, securities class action litigation has often been instituted against that company. If we were involved in any similar litigation, we could incur substantial costs and our management's attention and resources could be diverted, which could affect our business, financial condition and results of operations.

We may not be able to maintain our listing on the Nasdaq Global Market.

Our ordinary shares currently trade on the Nasdaq Global Market under the symbol "CLGN". If we fail to adhere to Nasdaq's strict listing criteria, including with respect to share price, market capitalization and stockholders' equity, our stock may be delisted. Our results of operations and our fluctuating stock price directly affects our ability to satisfy these listing standards. If we fail to do so, we may be subject to delisting. A delisting could adversely affect our ability to obtain financing for our operations or result in a loss of confidence by investors, customers, suppliers or employees. A delisting from the Nasdaq Global Market could result in our ordinary shares being listed on the Nasdaq Capital Market or on an over-the-counter market, each of which are generally considered to be a less efficient market than the Nasdaq Global Market. Although we currently satisfy the listing criteria for Nasdaq, if our stock price declines dramatically, we could be at risk of failing to meet the Nasdaq continued listing criteria.

We incur significant additional costs as a result of being a public company subject to SEC reporting requirements in the United States, and our management is required to devote substantial additional time to new compliance initiatives as well as to compliance with ongoing United States reporting requirements.

As a U.S. public reporting company, we are incurring significant additional accounting, legal, and other expenses in the future. Our management and other personnel need to devote substantial time to the compliance requirements of being a U.S. public company; in addition, the implementation of such compliance processes and systems may require us to hire outside consultants and incur other significant costs. Any future changes in the laws and regulations affecting public companies in the United States and the rules and regulations adopted by the SEC and the Nasdaq Global Market, for so long as they apply to us, will result in increased costs to us as we respond to such changes. These laws, rules, and regulations could make it more difficult or more costly for us to obtain certain types of insurance, including director and officer liability insurance, and we may be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, on our board committees, if any, or as senior management.

Our principal shareholders, management and directors beneficially own a significant percentage of our ordinary shares and will be able to exert significant influence over matters subject to shareholder approval.

As of March 15, 2025, our senior management, directors, and five percent or more shareholders and their affiliates beneficially owned approximately 33% of our ordinary shares and an additional 6% in options exercisable into ordinary shares. These shareholders will be able to significantly influence all matters requiring shareholder approval, except for decisions that require a special majority at a shareholders' meeting. For example, these shareholders, if they were to act together, may be able to significantly influence elections of directors (other than our external directors, within the meaning of Israeli law, as described under "Management—External Directors"), amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our ordinary shares that you may believe are in your best interest as one of our shareholders.

If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, our shareholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our ordinary shares.

Effective internal controls over financial reporting are necessary for us to provide reliable financial reports. Together with adequate disclosure controls and procedures, effective internal controls are designed to prevent fraud. Any failure to implement required new or improved controls or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. In addition, any testing by us conducted in connection with Section 404 of the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses, may require prospective or retroactive changes to our financial statements, or may identify other areas for further attention or improvement. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our ordinary shares.

Section 404 of the Sarbanes-Oxley Act requires our management to report on the effectiveness of our internal control structure and procedures for financial reporting. In addition, as long as we do not become an accelerated or large accelerated filer, we are exempt from the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act. Under this exemption, our auditor will not be required to attest to and report on our management's assessment of our internal control over financial reporting until the date we are no longer a non-accelerated filer. We have an ongoing program to perform the system and process evaluation and testing necessary to continue to comply with these requirements. During the course of our review and testing, we may identify deficiencies and be unable to remediate them before we must provide the required reports. Furthermore, if we have a material weakness in our internal controls over financial reporting, we may not detect errors on a timely basis and our financial statements may be materially misstated. We may not be able to conclude on an ongoing basis that we have effective internal control over financial reporting, which could harm our operating results, cause investors to lose confidence in our reported financial information and cause the trading price of our share to fall.

To build our finance infrastructure, we may need to improve our accounting systems, disclosure policies, procedures and controls. If we are unsuccessful in building an appropriate accounting infrastructure, we may not be able to prepare and disclose, in a timely manner, our financial statements and other required disclosures, or comply with existing or new reporting requirements. Any failure to report our financial results on an accurate and timely basis could result in sanctions, lawsuits, delisting of our shares from the Nasdaq Global Market or other adverse consequences that would materially harm our business. If we cannot provide reliable financial reports or prevent fraud, our business and results of operations could be harmed and investors could lose confidence in our reported financial information.

We are a "foreign private issuer," and we cannot be certain if the reduced reporting requirements applicable to foreign private issuers will make our ordinary shares less attractive to investors.

As a foreign private issuer, we are not subject to the same requirements that are imposed upon U.S. domestic issuers by the SEC. Under the Securities Exchange Act of 1934, as amended, or the Exchange Act, we will be subject to reporting obligations that, in certain respects, are less detailed and less frequent than those of U.S. domestic reporting companies. For example, we will not be required to issue proxy statements that comply with the requirements applicable to U.S. domestic reporting companies. We will also have four months after the end of each fiscal year to file our Annual Reports with the SEC and will not be required to file current reports as frequently or promptly as U.S. domestic reporting companies. Furthermore, our officers, directors, and principal shareholders will be exempt from the requirements to report transactions in our equity securities and from the short-swing profit liability provisions contained in Section 16 of the Exchange Act. These exemptions and leniencies, along with other corporate governance exemptions resulting from our ability to rely on home country rules, will reduce the frequency and scope of information and protections to which you may otherwise have been eligible in relation to U.S. domestic reporting companies. See "Item 16G. Corporate Governance Practices" for more information, including regarding reliefs relating to general meetings for companies whose securities are traded outside of Israel.

We cannot predict if investors will find our ordinary shares less attractive because we may rely on these reduced requirements. If some investors find our ordinary shares less attractive as a result, there may be a less active trading market for our ordinary shares and our share price may be more volatile.

Sales of a substantial number of our ordinary shares in the public market could cause our share price to fall.

If our existing shareholders sell, indicate an intention to sell, or the market perceives that they intend to sell, substantial amounts of our securities on the Nasdaq Global Market after the date of this Annual Report on Form 20-F, the market price of our securities could decline significantly. As of March 15, 2025, we had 11,454,512 ordinary shares outstanding. In addition, as of March 15, 2025, an aggregate of 1,415,074 ordinary shares, that are issuable pursuant to exercise of outstanding options, will become eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules, Rule 144 and Rule 701 under the Securities Act of 1933, as amended, or the Securities Act. If these additional ordinary shares are sold, or if it is perceived that they will be sold, in the public market, the market price of our ordinary shares could decline.

Future sales and issuances of our securities or rights to purchase securities, including pursuant to our equity incentive plans, could result in additional dilution of the percentage ownership of our shareholders and could cause the prices of our securities to fall.

Additional capital will be needed in the future to continue our planned operations. To the extent we raise additional capital by issuing equity securities, our shareholders may experience substantial dilution. We may sell ordinary shares, convertible securities, or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell ordinary shares, convertible securities, or other equity securities in one or more transactions, existing investors may be materially diluted by subsequent sales, and new investors could gain rights superior to our existing shareholders.

Pursuant to our Share Ownership and Option Plan (2010), or the 2010 Plan and our 2024 Share Award Plan, or the 2024 Plan, our management is authorized to grant share options, restricted share units and other equity-based awards to our employees, officers, directors, and consultants. As of March 15, 2025, our officers, directors, employees and consultants hold options to purchase 1,699,693 and 34,000 ordinary shares under the 2010 Plan and the 2024 Plan, respectively. Additionally, as of March 15, 2025, our officers, directors, and certain employees have been granted 426,000 restricted share units under the 2024 Plan. If our board of directors elects to issue additional options, restricted share units or other equity-based awards under the 2010 Plan or the 2024 Plan, our shareholders may experience additional dilution, which could cause our share price to fall.

We do not intend to pay dividends on our securities in the foreseeable future, so any returns will be limited to the value of our shares.

We have never declared or paid any cash dividends on our share capital. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Any return to shareholders will therefore be limited to the appreciation of their shares. In addition, Israeli law limits our ability to declare and pay dividends, and may subject our dividends to Israeli withholding taxes; see "Item 10.B. Memorandum and Articles of Association—Dividend and Liquidation Rights" and "Item 16G. Corporate Governance Practices" for additional information. As a result, investors in our ordinary shares will not be able to benefit from owning these securities unless their market price becomes greater than the price paid by such investors and they are able to sell such securities. We cannot assure you that you will ever be able to resell our securities at a price in excess of the price paid.

Your percentage ownership in us may be diluted by future issuances of share capital, which could reduce your influence over matters on which shareholders vote.

Our board of directors will have the authority, in most cases without action or vote of our shareholders, to issue all or any part of our authorized but unissued shares, including ordinary shares issuable upon the exercise of outstanding options and warrants. Issuances of additional shares would reduce your influence over matters on which our shareholders vote.

If equity research analysts do not publish research reports about our business or if they issue unfavorable commentary or downgrade our ordinary shares, the price of our ordinary shares could decline.

The trading market for our ordinary shares will rely in part on the research and reports that equity research analysts publish about us and our business. The price of our ordinary shares could decline if we do not obtain research analyst coverage or if one or more securities analysts downgrade our ordinary shares, issue other unfavorable commentary, or cease publishing reports about us or our business.

Risks Related to Our Operations in Israel

We are a "foreign private issuer" and intend to follow certain home country corporate governance practices, and our shareholders may not have the same protections afforded to shareholders of companies that are subject to all corporate governance requirements under the listing rules of the Nasdaq Stock Market LLC, or the Nasdaq Listing Rules.

As a foreign private issuer, we are permitted to follow certain home country corporate governance practices instead of those otherwise required under the Nasdaq Stock Market for domestic U.S. issuers. For instance, we follow home country practice in Israel with regard to the quorum requirement for shareholder meetings. As permitted under the Israeli Companies Law of 1999, or the Companies Law, our articles of association provide that the quorum for any meeting of shareholders shall be the presence of at least two shareholders present in person, by proxy, or by a voting instrument, who hold at least 20% of the voting power of our shares. In addition, we will follow home country practices in Israel (and consequently avoid the requirements that would otherwise apply to a U.S. company listed on the Nasdaq Global Market) with regard to the requirement to obtain shareholder approval for certain dilutive events (such as for the establishment or amendment of certain equity-based compensation plans, issuances that will result in a change of control of the company, certain transactions, and certain acquisitions of the stock or assets of another company). We may in the future (or may be required to) elect to follow home country practices in Israel with regard to other matters. Following our home country governance practices as opposed to the requirements that would otherwise apply to a U.S. company listed on the Nasdaq Global Market may provide less protection to you than what is accorded to investors under the Nasdaq Listing Rules applicable to domestic U.S. issuers. See "Item 16G. Corporate Governance Practices" for more information.

In addition, as a foreign private issuer, we are exempt from the rules and regulations under the Exchange Act related to the furnishing and content of proxy statements. Under regulations promulgated under the Companies Law, we will be required to disclose in the notice for our annual meetings of shareholders if we had not already done so in our annual report, the annual compensation of our five most highly compensated officers on an individual basis, rather than aggregate. However, this disclosure will not be as extensive as the disclosure required by a U.S. domestic issuer. We will also have four months after the end of each fiscal year to file our annual reports with the SEC and will not be required to file current reports as frequently or promptly as U.S. domestic reporting companies. Furthermore, as a foreign private issuer, our officers, directors and principal shareholders will be exempt from the requirements to report short-swing profit recovery contained in Section 16 of the Exchange Act. Also, as a foreign private issuer, we are not subject to the requirements of Regulation FD (Fair Disclosure) promulgated under the Exchange Act. These exemptions and leniencies will reduce the frequency and scope of information and protections available to you in comparison to those applicable to U.S. domestic reporting companies.

In order to maintain our current status as a foreign private issuer, more than 50% of our outstanding voting securities must not be directly or indirectly owned by residents of the U.S., and we must not have any of the following: (i) a majority of our executive officers or directors being U.S. citizens or residents, (ii) more than 50% of our assets being located in the U.S., or (iii) our business being principally administered in the U.S. Although we have elected to comply with certain U.S. regulatory provisions, our loss of foreign private issuer status would make such provisions mandatory. The regulatory and compliance costs to us under U.S. securities laws as a U.S. domestic reporting company may be significantly higher. If we are not a foreign private issuer, we will be required to file periodic reports and registration statements on U.S. domestic reporting company forms with the SEC, which are more detailed and extensive than the forms available to a foreign private issuer. We may also be required to modify certain of our policies to comply with accepted governance practices associated with U.S. domestic reporting companies. Such conversion and modifications will involve additional costs. In addition, we may lose our ability to rely upon exemptions from certain corporate governance requirements on U.S. stock exchanges that are available to foreign private issuers.

Potential political, economic, and military instability in the State of Israel, where the majority of our senior management and our research and development facilities are located, may adversely impact our results of operations.

We are incorporated under Israeli law and our offices and operations are located in the State of Israel. In addition, our employees, officers, and all but three of our directors are residents of Israel. Accordingly, political, economic, and military conditions in Israel directly affect our business. Since the State of Israel was established in 1948, a number of armed conflicts have occurred between Israel and its neighboring countries.

In particular, in October 2023, Hamas terrorists infiltrated Israel's southern border from the Gaza Strip and conducted a series of attacks on civilian and military targets. Hamas also launched extensive rocket attacks on the Israeli population and industrial centers located along Israel's border with the Gaza Strip and in other areas within the State of Israel. These attacks resulted in thousands of deaths and injuries, and Hamas additionally kidnapped many Israeli civilians and soldiers. As a result of the events of October 7, 2023, the Israeli government declared that the country was at war and several hundred thousand Israeli military reservists were drafted to perform immediate military service, including at the time about 10% of our workforce in Israel. Although many of such military reservists have since been released, they may be called up for additional reserve duty, depending on developments in the war in Gaza and along Israel's other borders. Military service call ups that result in absences of personnel for an extended period of time may materially and adversely affect our business, prospects, financial condition and results of operations. As of March 15, 2025, we currently have 57 employees located in Israel.

Since the commencement of these events, there have been continued hostilities along Israel's northern border with the Hezbollah terror organization), with the Houthis in Yemen and on other fronts with various extremist groups in the region, such as various rebel militia groups in Syria and Iraq. In October 2024, Israel began limited ground operations against Hezbollah in Lebanon, and in November 2024, a ceasefire was brokered between Israel and Hezbollah. It is possible that hostilities with Iran, Hamas, Hezbollah, the Houthis and Syria will escalate, and that other terrorist organizations, including Palestinian military organizations in the West Bank, will join the hostilities. In addition, in April 2024 and on October 1, 2024 Iran launched direct attacks on Israel involving hundreds of drones and missiles, has threatened to continue to attack Israel, and is widely believed to be developing nuclear weapons. Iran is also believed to have a strong influence among extremist groups in the region, such as Hamas in Gaza, Hezbollah in Lebanon, the Houthis in Yemen and various rebel militia groups in Syria and Iraq. These situations may potentially escalate in the future to more violent events which may affect Israel and us. Any hostilities, armed conflicts, terrorist activities involving Israel or the interruption or curtailment of trade between Israel and its trading partners, or any political instability in the region could adversely affect business conditions and our results of operations and could make it more difficult for us to raise capital and could adversely affect the market price of our ordinary shares. An escalation of tensions or violence might result in a significant downturn in the economic or financial condition of Israel, which could have a material adverse effect on our operations in Israel and our business.

While to date, we have not experienced any major disruptions in our operations due to the war, during 2024 we took precautionary measures to close our facility in Yessod Hama'ala, which is located approximately 9km from Israel's northern border with Lebanon, for an extended period although it is now operational. Due to the close proximity of our facility in Yessod Hama'ala to the border, if our Yessod facility were to sustain damage and/or we are required to partially or completely close the facility for an indefinite period of time it could have a material impact on our business and results of operations. However, the intensity and duration of the current war in Israel is difficult to predict at this stage, as are such war's economic implications on our business and operations and on Israel's economy in general, and we continue to monitor the situation closely and examine the potential disruptions that could adversely affect our operations.

Our commercial insurance does not cover losses that may occur as a result of events associated with war and terrorism. Although the Israeli government currently covers the reinstatement value of direct damages that are caused by terrorist attacks or acts of war, we cannot assure you that this government coverage will be maintained or that it will sufficiently cover our potential damages. Any losses or damages incurred by us could have a material adverse effect on our business. Any armed conflicts or political instability in the region would likely negatively affect business conditions and could harm our results of operations.

The continued political instability and hostilities between Israel and its neighbors and any future armed conflict, terrorist activity or political instability in the region could adversely affect our operations in Israel and adversely affect the market price of our shares of common stock. In addition, several organizations and countries may restrict doing business with Israel and Israeli companies have been and are today subjected to economic boycotts. The interruption or curtailment of trade between Israel and its present trading partners could adversely affect our business, financial condition and results of operations.

Finally, political conditions within Israel may affect our operations. Israel has held five general elections between 2019 and 2022, and prior to October 2023, the Israeli government pursued extensive changes to Israel's judicial system, which sparked extensive political debate and unrest. To date, the main initiatives have been substantially put on hold. Actual or perceived political instability in Israel or any negative changes in the political environment, may individually or in the aggregate adversely affect the Israeli economy and, in turn, our business, financial condition, results of operations and growth prospects.

The tax benefits that are available to us if and when we generate taxable income require us to meet various conditions and may be prevented or reduced in the future, which could increase our costs and taxes.

If and when we generate taxable income, we may be eligible for certain tax benefits provided to "Preferred Enterprises" under the Israeli Law for the Encouragement of Capital Investments, 5719-1959, as amended, or the Investment Law. The benefits that may be available to us under the Investment Law are subject to the fulfillment of conditions stipulated in the Investment Law. Further, in the future these tax benefits may be reduced or discontinued. If these tax benefits are reduced, cancelled, or discontinued, our Israeli taxable income would be subject to regular Israeli corporate tax rates. The standard corporate tax rate for Israeli companies is currently 23%. Additionally, if we increase our activities outside of Israel through acquisitions, for example, our expanded activities might not be eligible for inclusion in future Israeli tax benefit programs. See "Item 10.E. Taxation—Israeli Tax Considerations and Government Programs—Law for the Encouragement of Capital Investments, 5719-1959."

It may be difficult to enforce a U.S. judgment against us, our officers and directors, and the Israeli experts named in this Annual Report on Form 20-F in Israel or the United States, or to assert U.S. securities laws claims in Israel or serve process on our officers and directors and these experts.

We were incorporated in Israel, and our corporate headquarters, research facilities and substantially all of our operations are located in Israel. All of our senior management and a majority of our directors are located outside the United States. All of our assets are located outside the United States. Therefore, it may be difficult for an investor, or any other person or entity, to enforce a U.S. court judgment based upon the civil liability provisions of the U.S. federal securities laws against us or any of these persons in a U.S. or Israeli court, or to effect service of process upon these persons in the United States. Additionally, it may be difficult for an investor, or any other person or entity, to assert U.S. securities law claims in original actions instituted in Israel. Israeli courts may refuse to hear a claim based on an alleged violation of U.S. securities laws against us or our officers and directors on the grounds that Israel is not the most appropriate forum in which to bring such a claim. Even if an Israeli court agrees to hear a claim, it may determine that Israeli law and not U.S. law is applicable to the claim. If U.S. law is found to be applicable, the content of applicable U.S. law must be proved as a fact by expert witnesses, which can be a time-consuming and costly process. Certain matters of procedure would be governed by Israeli law. There is little binding case law in Israel addressing the matters described above.

Your rights and responsibilities as our shareholder will be governed by Israeli law, which may differ in some respects from the rights and responsibilities of shareholders of U.S. corporations.

Because we are incorporated under Israeli law, the rights and responsibilities of our shareholders are governed by our articles of association and Israeli law. These rights and responsibilities differ in some material respects from the rights and responsibilities of shareholders of U.S. corporations. In particular, a shareholder of an Israeli company has a duty to act in good faith and in a customary manner in exercising its rights and performing its obligations towards the company and other shareholders and to refrain from abusing its power in the company, including, among other things, in voting at the general meeting of shareholders on certain matters, such as an amendment to the company's articles of association, an increase of the company's authorized share capital, a merger of the company, and approval of related party transactions that require shareholder approval. A shareholder also has a general duty to refrain from discriminating against other shareholders. In addition, a controlling shareholder or a shareholder who knows that it possesses the power to determine the outcome of a shareholder vote or to appoint or prevent the appointment of an officer of the company has a duty of fairness towards the company. However, Israeli law does not define the substance of this duty of fairness. There is limited case law available to assist us in understanding the nature of this duty or the implications of these provisions. These provisions may be interpreted to impose additional obligations and liabilities on our shareholders that are not typically imposed on shareholders of U.S. corporations. See "Item 6.C. Board Practices—Approval of Related Party Transactions under Israeli Law—Shareholders' Duties."

Provisions of Israeli law and our amended and restated articles of association could make it more difficult for a third party to acquire us or increase the cost of acquiring us, even if doing so would benefit our shareholders.

Israeli law regulates mergers, requires tender offers for acquisitions of shares above specified thresholds, requires special approvals for transactions involving directors, officers, or significant shareholders and regulates other matters that may be relevant to such types of transactions. For example, a tender offer for all of a company's issued and outstanding shares, or a Full Tender Offer, can only be completed if the acquirer receives approval of the holders of at least 95% of the issued share capital. Completion of the Full Tender Offer also requires approval of a majority of the offerees that do not have a personal interest in the tender offer, unless at least 98% of the company's outstanding shares are tendered. Furthermore, the shareholders, including those who indicated their acceptance of the Full Tender Offer (unless the acquirer stipulated in its tender offer that a shareholder that accepts the offer may not seek appraisal rights), may, at any time within six months following the completion of the tender offer, petition an Israeli court to alter the consideration for the acquisition. In case the Full Tender Offer has not been accepted by the required threshold, the offeror is limited to acquire shares that will confer on the offeror a holding of not more than 90% of the issued share capital of the company. In addition, special tender offer requirements may also apply upon a purchaser becoming a holder of 25% or more of the voting rights in a company (if there is no other shareholder of the company holding 25% or more of the voting rights in the company) or upon a purchaser becoming a holder of more than 45% of the voting rights in the company (if there is no other shareholder of the company who holds more than 45% of the voting rights in the company), See "Item 10.B. Memorandum and Articles of Association—Acquisitions under Israeli Law" for additional information.

Further, Israeli tax considerations may make potential transactions undesirable to us or to some of our shareholders whose country of residence does not have a tax treaty with Israel granting tax relief to such shareholders from Israeli tax. For example, Israeli tax law does not recognize tax-free share exchanges to the same extent as U.S. tax law. With respect to mergers, Israeli tax law allows for tax deferral in certain circumstances but makes the deferral contingent on the fulfilment of a number of conditions, including, in some cases, a holding period of two years from the date of the transaction during which sales and dispositions of shares of the participating companies are subject to certain restrictions. Moreover, with respect to certain share swap transactions, the tax deferral is limited in time, and when such time expires, the tax becomes payable even if no disposition of the shares has occurred.

We have received grants from the IIA for certain research and development expenditures. The terms of these grants may require us to satisfy specified conditions in order to manufacture products and transfer technologies outside of Israel. For more information, see "—Risks Related to Our Financial Condition and Capital Requirements—The IIA grants we have received in the past for research and development expenditures may restrict our ability to manufacture products and transfer know-how outside of Israel and require us to satisfy specified conditions."

We may be classified as a passive foreign investment company for U.S. federal income tax purposes, and our U.S. shareholders may suffer adverse tax consequences as a result.

Generally, if, for any taxable year, either, at least 75% of our gross income is passive income (including our pro-rata share of the gross income of our 25% or more-owned corporate subsidiaries), or at least 50% of the average value of our assets (including our pro-rata share of the assets of our 25% or more-owned corporate subsidiaries) is attributable to assets that produce passive income or are held for the production of passive income, we would be characterized as a passive foreign investment company, or PFIC, for U.S. federal income tax purposes. Passive income generally includes dividends, interest, and gains from disposition of passive assets and rents and royalties.

If we are characterized as a PFIC for any taxable year (or portion thereof) that is included in the holding period of a U.S. holder (as defined below) of our securities, such U.S. holder generally will be subject to certain adverse U.S. federal income tax consequences, including increased tax liability on gains from dispositions of our securities and certain distributions and a requirement to file annual reports with the Internal Revenue Service, or IRS. Certain adverse consequences of PFIC status may be alleviated if a U.S. holder makes a "mark to market" election or an election to treat us as a qualified electing fund, or QEF. These elections would result in an alternative treatment (such as mark-to-market treatment) of our ordinary shares. It is not expected that a U.S. holder will be able to make a QEF election because we do not intend to provide U.S. holders with the information necessary to make a QEF election. See "Item 10.E. Taxation—Certain Material U.S. Federal Income Tax Consequences—Passive Foreign Investment Company Consequences."

Since PFIC status depends on the composition of our income and the composition and value of our assets (which may be determined in large part by reference to the market value of our ordinary shares, which may be volatile) from time to time, there can be no assurance that we will not be considered a PFIC for any taxable year. However, based on our non-passive revenue-producing operations for the year ended December 31, 2024, we do not believe we were a PFIC for our 2024 taxable year. Because the PFIC determination is highly fact intensive, there can be no assurance that we were not a PFIC in 2024 and will not be a PFIC in 2025 or any other year.

U.S. investors are urged to consult their own tax advisors regarding the possible application of the PFIC rules. For more information, see "Item 10.E. Taxation—Certain Material U.S. Federal Income Tax Consequences—Passive Foreign Investment Company Consequences."

If a United States person is treated as owning at least 10% of our shares, such holder may be subject to adverse U.S. federal income tax consequences.

If a United States person is treated as owning (directly, indirectly or constructively) at least 10% of the value or voting power of our shares, such person may be treated as a "United States shareholder" with respect to each "controlled foreign corporation" in our group (if any). A United States shareholder of a controlled foreign corporation may be required to annually report and include in its U.S. taxable income its pro rata share of "Subpart F income," "global intangible low-taxed income" and investments in U.S. property by controlled foreign corporations, whether or not we make any distributions, and may be subject to tax reporting obligations. An individual that is a United States shareholder with respect to a controlled foreign corporation generally would not be allowed certain tax deductions or foreign tax credits that would be allowed to a United States shareholder that is a U.S. corporation. A failure to comply with these reporting obligations may subject you to significant monetary penalties and may prevent the statute of limitations with respect to your U.S. federal income tax return for the year for which reporting was due from starting. We cannot provide any assurances that we will assist any shareholder in determining whether such shareholder is treated as a United States shareholder with respect to any "controlled foreign corporation" in our group (if any) or furnish to any United States shareholders information that may be necessary to comply with the aforementioned reporting and tax paying obligations. A United States investor should consult its tax advisors regarding the potential application of these rules to its investment in the shares.

Our facilities in Israel are subject to local Business Licensing and Planning and Zoning regulations and we may be subject to fines if not complied with.

Under the Israeli Licensing of Businesses Law, operating a business without a license or temporary permit is a criminal offense. Both our sites in Rehovot, Israel, and our production site at Yessod Hama'ala, Israel, have valid business licenses in effect.

In addition, the Israeli Planning and Zoning Law, sets provisions and obligations, *inter alia*, regarding the licensing process for a new building, including building permits, non-conforming use and easements, the supervision over its construction, and the required occupancy permits. According to the Planning and Zoning Law, work or use of land without a permit, where such permit is required, a deviation from the permit granted, or use of agricultural land in violation of the law constitute criminal offenses. We have recently learned upon internal inspection that permits for certain of the structures on our production site at Yessod Hama'ala are missing. We are in correspondence with the relevant authorities, including the regional council, and are in the process of obtaining the necessary permits. Nevertheless, the absence of such permits could lead to the halt or closure of the site, may expose us to legal proceedings and may constitute a criminal offence, and as such, could adversely impact our operations and results, including our production capabilities. To date, the site remains open and fully operational, and we have not experienced any adverse effects resulting from our need to obtain the said permits.

ITEM 4. INFORMATION ON THE COMPANY

A. History and Development of the Company

We are a regenerative and aesthetic medicine company focused on medical aesthetics and 3D bioprinting of tissues and organs. Our products are based on our recombinant human collagen (rhCollagen) that is produced with our proprietary plant based genetic engineering technology. These products address indications for the diverse fields of tissue repair, aesthetics and organ manufacturing, and are ushering in a new era in regenerative and aesthetic medicine.

Our legal and commercial name is CollPlant Biotechnologies Ltd. Our name has changed several times but has been CollPlant Biotechnologies Ltd. since June 21, 2019. We hold all of the issued and outstanding shares of CollPlant Ltd. CollPlant Ltd. was incorporated in Israel on August 12, 2004 as a private company limited by shares and began its operations as a technology incubator company under the IIA's technology incubators program. CollPlant Ltd. owns all of our intellectual property. CollPlant Ltd. holds all of the issued and outstanding shares of CollPlant Inc. CollPlant Inc. was incorporated in Delaware on November 30, 2021, as a corporation. CollPlant Biotechnologies Ltd. was incorporated in Israel on November 9, 1981 as a private company limited by shares. The Company became a public company in 1993, when all of its ordinary shares were listed on the TASE. CollPlant Ltd. was incorporated under the laws of the State of Israel in 2004 and merged with us (by way of transfer of shares) in 2010.

On May 25, 2021, our ordinary shares were approved for trading on the Nasdaq Global Market under our ticker symbol "CLGN" and began trading at the open of market on June 4, 2021. At such time, our ADSs, were mandatorily cancelled and exchanged for ordinary shares at a one-for-one ratio. Prior to that, our ADSs were quoted on the OTCQX from March 2015 to May 25, 2017, on the OTCQB from May 26, 2017 to January 30, 2018 and on the Nasdaq Capital Market from January 31, 2018 to June 3, 2021 under the symbol "CLGN". In 2018, we delisted our ordinary shares from trading on the TASE, and the last date of trading of our ordinary shares on the TASE was on October 29, 2018.

Our principal office is located at 4 Oppenheimer, Weizmann Science Park, Rehovot 7670104, Israel, and our telephone number is +972-73-232-5600. Our primary internet address is http://www.CollPlant.com. None of the information on our website is incorporated by reference herein. Puglisi & Associates serves as our agent for service of process in the United States for certain limited matters, and its address is 850 Library Avenue, Suite 204, Newark, Delaware 19711.

We use our website (http://www.CollPlant.com) as a channel of distribution of Company information. The information we post on our website may be deemed material. Accordingly, investors should monitor our website, in addition to following our press releases, SEC filings and public conference calls and webcasts. The contents of our website are not, however, a part of this Annual Report.

As a foreign private issuer, we are exempt from certain rules and regulations under the Exchange Act that are applicable to other public companies that are not foreign private issuers. For example, although we intend to report our financial results on a quarterly basis, we will not be required to issue quarterly reports, proxy statements that comply with the requirements applicable to U.S. domestic reporting companies, or individual executive compensation information that is as detailed as that required of U.S. domestic reporting companies. We will also have four months after the end of each fiscal year to file our annual report with the SEC and will not be required to file current reports as frequently or promptly as U.S. domestic reporting companies. Our senior management, directors, and principal shareholders will be exempt from the requirements to report transactions in our equity securities and from the short-swing profit liability provisions contained in Section 16 of the Exchange Act. As a foreign private issuer, we will also not be subject to the requirements of Regulation FD (Fair Disclosure) promulgated under the Exchange Act.

Our capital expenditures for December 31, 2024, 2023 and 2022 amounted to $0.5 million , $1 million, and $1.3 million, respectively. Our purchases of fixed assets primarily include laboratory equipment and establishment of our production site in Rehovot. We financed these expenditures primarily from cash on hand.

B. Business Overview

Overview

We are a regenerative and aesthetic medicine company focused on medical aesthetics and 3D bioprinting of tissues and organs. Our products are based on our recombinant human collagen (rhCollagen) that is produced in genetically engineered tobacco plants using our proprietary technology. These products address indications for the diverse fields of tissue repair and aesthetics, and are ushering in a new era in regenerative and aesthetic medicine.

In February 2021, we entered into the AbbVie Development Agreement with Allergan, an AbbVie company, pursuant to which we and AbbVie are collaborating in the development and commercialization of dermal and soft tissue filler products for the medical aesthetics market, using our rhCollagen technology in combination with AbbVie's technology. In February 2025, we announced the achievement of a development milestone with respect to this product candidate, which, according to the AbbVie Development Agreement, triggered a $2 million payment from AbbVie to us. This milestone achievement follows our announcement in June 2023 regarding another achievement which triggered a $10 million payment from AbbVie to us. The dermal filler product candidate is currently in the clinical phase. AbbVie is collecting data and conducting a review of interim results from the first cohort of patients enrolled under the trials initiated in 2023 and next steps for the program are to be determined by AbbVie upon concluding their assessment. The trials are designed, planned, and executed by AbbVie.

In the field of medical aesthetics, we are developing regenerative 3D-bioprinted breast implants for regeneration of breast tissue to address an unmet need derived from the estimated $3 billion global breast implant market. The implants in development are printed using bioink comprised of our rhCollagen in combination with other proprietary biomaterials. These implants are designed to regenerate breast tissue without eliciting immune response, and thus may provide a revolutionary alternative for aesthetic and reconstructive procedures, including postmastectomy for cancer patients. Pre-clinical studies are ongoing showing encouraging outcomes three months post implantation, with evidence of significant implant vascularization and rapid ingrowth of neo tissue, both of which are critical factors in enabling effective integration of the implant with the physiological system and supporting long-lasting regenerative processes. In addition, we are developing a photocurable regenerative dermal filler comprised of our tissue regenerating rhCollagen and other biomaterials. In addition to skin lifting, this state-of-the-art filler is designed to enable skin rejuvenation as well as facial contouring, thus addressing the need for more innovative aesthetic products. In this regard, in early 2023 we completed a 12-month preclinical study with our photocurable regenerative dermal filler, demonstrating superior tissue regeneration, lifting capacity and volume retention when compared to a commercial standard

In April 2023, we entered into a joint development and commercialization agreement with Stratasys pursuant to which we agreed to collaborate on the development of a solution to bio-fabrication human tissues and organs, using Stratasys' P3 technology-based bioprinter and our rhCollagen-based bioinks, with the first target being a development of an industrial-scale solution for CollPlant's regenerative breast implants project. In August 2024 we announced the initiation of a pre-clinical study with 200cc commercial-sized regenerative implants printed on a Stratasys Origin® 3D printer. We are expecting to have initial results from the study in the first half of 2025.

In January 2023, we commercially launched Collink.3D™50L in powder form, which is our first bioink available in powder form, joining Collink.3D™90 and Collink.3D™50 launched in 2022 and 2021, respectively. Collink.3D is our rhCollagen-based bioink platform, which is ideal for 3D bioprinting of tissues and organs for regenerative medicine applications. These rhCollagen-based bioink products are designed to allow the scalable and reproduceable biofabrication of scaffolds, tissues and organ transplants.

Our rhCollagen production process utilizes plant-based genetic engineering technology. This approach eliminates the need for traditional animal-derived collagen sources, reducing the environmental strain associated with traditional methods and promoting more ethical and sustainable practices.

In July, 2024, we announced the release of our inaugural Environmental, Social and Corporate Governance (ESG) and Sustainability Report covering the fiscal year 2023. The report reflects CollPlant's wide commitment to fostering environmental sustainability and enhancing human health, as well as advancing social and corporate governance objectives that contribute to the Company's impact.

Consistent with our mission of helping people live longer, healthier lives through regenerative medicine, we are committed to supporting a more sustainable ecosystem that benefits all stakeholders, including patients, our employees, and our shareholders.

We believe our technology is the only commercially viable technology available for the production of genetically engineered, or recombinant, human collagen. We believe that our rhCollagen is identical to the type I collagen produced by the human body, has significant advantages compared to currently marketed tissue-derived collagens, including improved bio-functionality, high homogeneity, and safety profile (does not elicit immune response). We believe the attributes of our rhCollagen make it suitable for numerous tissue and organ regeneration applications throughout the human body.

Our rhCollagen has superior biological function when compared to any tissue-derived collagens, whether from animal or human tissues, according to data published in peer-reviewed scientific publications. Our rhCollagen can be fabricated in different forms and shapes including bioinks, gels, pastes, sponges, sheets, membranes, fibers, and thin coats, all of which have been tested and proven superior to tissue-derived products. We have demonstrated that, due to its homogeneity, rhCollagen can produce bioinks with optimal rheological properties fibers with high molecular alignment, which enables the formation of tissue repair products with distinctive physical properties.

In December 2020, we entered into a product manufacturing and supply agreement with STEMCELL, under which we are selling our proprietary recombinant human Type I collagen (rhCollagen) to STEMCELL, which incorporates it into cell culture media kits. To date, hundreds of companies, as well as research and academic institutes, have used these kits for research and development projects. In January 2024, this agreement was extended to include the distribution of the STEMCELL kits globally for use not only in the regenerative medicine research market but for clinical purposes also.

We are currently focusing on the following innovative rhCollagen-based product pipeline:

- Regenerative dermal and soft tissue fillers. Our rhCollagen offers a portfolio of opportunities in the field of regenerative aesthetics, owing to its ideal structure and non-immunogenic properties that we believe provide the optimal scaffold to attract cells and promote tissue regeneration. We are collaborating with AbbVie in the development and commercialization of the dermal and soft tissue filler product for the medical aesthetics market, using our rhCollagen technology in combination with AbbVie's technology, pursuant to the AbbVie Development Agreement entered into in February 2021. In February 2025, we announced the achievement of a development milestone with respect to the dermal and soft tissue filler product, which, according to the AbbVie Development Agreement, triggered a $2 million payment from AbbVie to CollPlant. The announcement of this milestone follows our announcement in June 2023, of the achievement of another major milestone with respect to this product candidate, which triggered a $10 million payment from AbbVie to us that was received in July 2023. In addition, we are developing a photocurable regenerative dermal filler comprised of our tissue regenerating rhCollagen and other biomaterials. In addition to skin lifting this state-of-the-art filler is designed to enable skin rejuvenation as well as facial contouring, thus addressing the need for more innovative aesthetic products. In this regard, in early 2023 we completed a 12-month preclinical study with our photocurable regenerative dermal filler, demonstrating superior tissue regeneration, lifting capacity and volume retention when compared to a commercial standard.

- ***3D-bioprinted regenerative breast implants.*** We are developing a biocompatible commercial-sized, 3D-bioprinted regenerative breast implants, which are designed to gradually degrade and be replaced by newly grown natural breast tissue. Pre-clinical studies on large animals are showing encouraging outcomes three months post implantation, with evidence of significant implant vascularization and rapid ingrowth of native tissue, both of which are critical factors in enabling effective integration of the implant with the physiological system and supporting long-lasting regenerative processes.

  We were in the initial stages of developing injectable breast implants, and a 3D-bioprinted Regenerative soft Tissue Matrix, or RTM for use in breast reconstruction procedures in combination with an implant. However, we decided to temporarily defer the development of both these products in order to concentrate our efforts on advancing the development of our 3D-bioprinted regenerative breast implants. We will consider resuming the development of both the injectable breast implants and RTM based on our 3D-bioprinted breast implant program progress.

- ***CollPlant rhCollagen-based Commercial Bioink for Regenerative Medicine Applications.*** Our bioink product line provides an ideal building block for three dimensional bioprinting of tissues and organs. The bioink is intended to enable the printing of three-dimensional scaffolds combined with human cells and/or growth factors as a basis for tissue or organ formation. In addition to collagen, CollPlant's bioink formulations can include other proteins and/or polymers as well. Our bioink is being developed to be compatible with numerous 3D bioprinting technologies and with printed organ characteristics. In January 2023, we launched Collink.3D™ 50L in powder form, which is our first bioink available in powder form and provides enhanced operational flexibility to support a wide range of 3D bioprinting applications, including drug discovery, drug screening, tissue testing as well as the development of transplantable tissues and organs. Earlier, in November 2022 we launched Collink.3D™ 90, an rhCollagen-based bioink solution for use in a variety of 3D bioprinting applications, offering increased mechanical properties to address additional printing requirements of soft and hard tissues. Collink.3D™ 90 is complementary to our first commercial bioink, Collink.3D 50, which was launched in November 2021, for use in 3D bioprinting. Collink.3D 50, our first commercially available rhCollagen-based bioink product is designed to allow the scalable and reproduceable biofabrication of scaffolds, tissues and organ transplants. Made entirely from human-derived collagen, Collink.3D bioinks enables the production of scaffolds that accurately mimic the physical properties of human tissues and organs, with improved bio-functionality, safety and reproducibility.

We also market VergenixSTR, a soft tissue matrix, intended for the treatment of tendinopathy, and VergenixFG, a wound healing flowable gel, intended for the treatment of chronic and acute wounds. In February 2025, we announced the expansion of our distribution channels for Vergenix STR product in Europe and Asia. Specifically, we signed distribution agreements for VergenixSTR with distributor companies located in the Netherlands, Turkey and India, for sales in the territories of the Netherlands, Belgium, Luxemburg ("Benelux"), Spain, India and Turkey.

We were in the initial stages of developing 'gut-on-a-chip' tissue model intended to enable a predictive and personalized treatment for inflammatory bowel diseases (IBD). In November 2022, we entered into a license and research agreement with Tel Aviv University and Sheba Medical Center hospital, to co-development a 'gut-on-a-chip', tissue model for drug discovery and high throughput screening of drugs. In November 2023, we elected to terminate the aforementioned agreement and continued to develop this program on our own. In March 2024, following a further assessment, we decided to focus our resources in advancing our 3D-bioprinted regenerative breast implants and dermal and soft tissue fillers programs, consequently putting the 'gut-on-a-chip' program on hold. We intend to revisit the 'gut-on-a-chip' program and consider its initiation once resources become available.

Collagen and Collagen-Based Products

Collagen is the main component of connective tissue and is the most abundant protein in mammals. In humans, it comprises approximately 30% of the protein found in the body. Due to its unique characteristics and diverse profile in human body functions, collagen is frequently selected from a variety of biocompatible materials for use in tissue repair to support structural integrity, induce cellular infiltration and promote healing. We estimate that the size of the market for human collagen-based tissue repair with our bioinks and aesthetic medicine product line exceeded $10 billion in 2021 and is estimated to reach approximately $18 billion in 2026.

Type I collagen is the most abundant form of collagen in the human body. It is the dominant constituent of connective tissue and serves as the primary scaffold in tissue or organ repair processes, making it a logical choice for regenerative medicine products. It is found in tendons, skin, artery walls, corneas, the endomysium surrounding muscle fibers, fibrocartilage, and the organic part of bones and teeth. Type II collagen is primarily found in articular cartilage. Type III collagen, which is produced quickly by young fibroblasts before the tougher type I collagen is synthesized, is found in granulation tissue such as artery walls, skin, intestines, and the uterus. While there may be some niche applications in the future where type III or possibly type II collagen is appropriate, type I collagen is best suited for applications associated with regenerative medicine because of its essential role in the healing process of bones, skin, and tendons. Type III rhCollagen is currently available for the research market, and is not used in any products currently approved for medical use.

Disadvantages of Current Collagen-Based Products

Currently, type I collagen for medical use is primarily tissue-derived from bovine (cow) and porcine (pig) sources, as well as from human cadavers. It is extracted from the tissues using mechanical processes and chemical treatments. Tissue-derived collagens suffer from a number of disadvantages:

- The harsh chemical conditions required to recycle collagen from mature tissue results in a collagen product with random defects in its protein structure, leading to a compromised triple helix. Consequently, tissue-derived collagens have significant damage to binding sites for progenitor cells, which are required for cell proliferation and differentiation into tissue.

- Tissue-derived collagens are non-homogenous and contains high proportions of cross-linked collagen species with high molecular weight. The rate of degradation of collagen is based on the proportion of cross-linked collagen species within the product. Excessive proportions of cross-linked collagen can impair the collagen's ability to self-assemble homogenous scaffolds with a high surface area and fully functional integrin-binding capacity, and can also impede its rate of degradation. The inability to effectively control the level of cross-linked collagen species in tissue-derived collagens results in variability of performance for a given product, and affects the rate of infiltration of cells into the scaffold, which can delay healing.

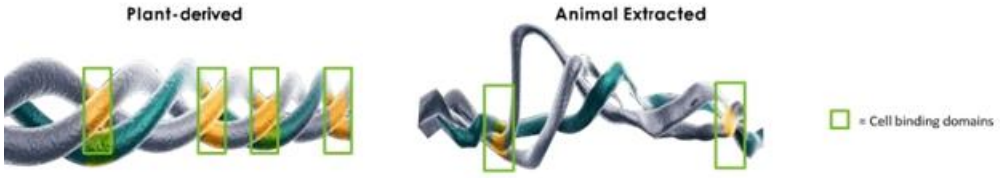
- The extraction of collagen from mature mammalian tissues leaves, in many cases, contaminant proteins, growth factors, and cytokines. As a result, scaffolds made of tissue-derived collagens may provoke inflammation, as well as undesirable immune and foreign body responses that may cause adverse effects and unpredictable biological outcomes.

- Extraction from animals or humans is also associated with risk of disease transmission. Since 2007, the FDA has highlighted the risks of transmissible diseases to humans in medical devices that contain materials derived from animal sources. In January 2014, the FDA released draft guidance suggesting precautionary procedures to be used in the production of medical devices containing materials derived from animal sources.

- Although collagen molecules are similar among various animal species, slight differences in the protein sequence between species may result in different biological behavior when applied to humans, and in some cases, invoke specific immune responses; for example, bovine collagen is associated with hypersensitivity and allergic reactions in approximately 3% of people.

Advantages of our rhCollagen and rhCollagen-based Products

All of our products are based on our proprietary recombinant type I human collagen, rhCollagen, though laboratory-derived, is identical to the type I collagen produced by the human body. The graphic below illustrates the structural differences between rhCollagen produced with our proprietary plant-based technology and currently marketed tissue-derived collagens.



The key advantages of products using our rhCollagen, as compared to those using collagen derived from animals or human cadaveric tissue, include:

- ***Better biofunctionality in tissue regeneration.*** Our rhCollagen has superior biological function when compared to animal or human tissue-derived collagen and has a number of useful physical characteristics, including thermal stability, or resistance to decomposition at high temperatures, and a pristine triple helix, according to data published in peer-reviewed scientific publications. The triple helix structure of collagen is formed when two α-1 protein chains and one α-2 protein chain wind together along a common axis. In the formation of rhCollagen, this structure is achieved without modifications that can lead to defects in the triple helix structure in human tissue-derived collagen, hereby leading to a pristine triple helix identical to the form found in nature. A pristine triple helix enables superior binding, which accelerates primary human cell proliferation. Collagen scaffolds of our rhCollagen support endothelial, fibroblast, and keratinocyte cell attachment and proliferation. In all cell types tested, cell proliferation was significantly better in scaffolds made of rhCollagen than in commercially available scaffolds made of bovine collagen. The accelerated cell proliferation achieved with our rhCollagen results in faster wound healing, less scarring, and higher quality tissue regeneration.

- ***High homogeneity.*** Because our rhCollagen is synthesized by five human genes in tobacco plants producing pure molecules that are repeatable and identical to type I human collagen, it is more homogenous than collagen derived from animal or human tissue sources. The high level of homogeneity of our rhCollagen allows the formulation of extremely high concentrations of monomeric, or single-molecule, collagen, up to 150-200mg/ml, which is at least 10 to 100 times higher than the concentration achieved with tissue-derived collagen. The high concentration of homogeneous monomeric collagen is of particular importance where strong collagen fibers are needed for 3D scaffolds. The homogeneity of our rhCollagen enables us to engineer consistent and reproducible products with a controlled degradation rate which can be optimized to the targeted indication. Achieving the same level of engineered performance would be difficult, if not impossible, with tissue-derived collagen that varies from batch to batch.

- ***Improved safety and greater purity.*** Our pure rhCollagen does not induce an immunogenic response, whereas impurities carried over from the source of tissue-derived collagen can lead to immune system rejection. *In vitro* studies performed under an academic collaboration have demonstrated that rhCollagen incubated with activated THP1-macrophages produces significantly lower levels of inflammatory cytokines when compared with bovine collagen that is similarly incubated. This demonstrates that animal-derived collagen can provoke a foreign body response not seen with rhCollagen, which delays healing and increases scarring. Further, with our rhCollagen, there are no potential side effects in the growth of tissue because there are no residues of growth factors. In addition, with tissue-derived collagen, there is a possibility that the animal or human from which the collagen was produced was infected with a virus, prion, or other pathogen. With our rhCollagen there is no known risk of transmitting diseases and pathogens.

- ***Novel applications.*** Due to our ability to control the protein at the molecular level, it is possible to use our rhCollagen to produce products with unique physical features, as well as high repeatability, which is not possible with tissue-derived collagen. As compared to tissue-derived collagen, rhCollagen membranes have shown better thermal stability, improved tensile strength due to alignment of the collagen fibers, and higher levels of transparency. In addition, rhCollagen can be used to produce high concentration solutions of collagen at low viscosities. The unique properties of our rhCollagen make it an ideal building block for many products that we believe cannot currently be produced using tissue-derived collagen, such as BioInks for 3D printing, artificial tendons, and transparent ophthalmic products.

We believe the clinical attributes of our rhCollagen will translate into benefits for patients, payors, and physicians, and will be adopted rapidly by the market. We believe the improved biofunctionality of our products could lead to faster recovery, better clinical outcomes, and reduced hospitalization time. Our *in vivo* studies have shown faster tissue remodeling, faster wound closure, and reduced scarring compared to competing products made from tissue-derived collagen.

The advantages of our rhCollagen outlined above have been demonstrated through *in vitro* testing and in preclinical animal studies, and are based on the performance of rhCollagen alone. The performance demonstrated in these studies is not necessarily indicative of the performance of our products which contain rhCollagen. We cannot assure you that the same advantages of rhCollagen will be seen in clinical testing of our products and product candidates containing rhCollagen.

We can produce our rhCollagen cost-effectively and have access to an abundant supply of raw materials. Tobacco is a relatively easy plant to grow, and can be cultivated in a wide range of climates and soils. The tobacco plant is an extremely hardy plant, may be grown in very large volumes and its growth time to reach desired maturity is relatively short (about eight weeks). Under our current production technology, we are able to achieve a cost of goods that allows us to offer products at prices that are competitive with tissue-derived collagen.

Collagen-based products are already used extensively in the marketplace; therefore, we expect our product candidates, except for dermal fillers, will likely be eligible for reimbursement by third-party payors, including government agencies and insurance companies. We believe that the demand for tissue-derived collagen will decrease as the market recognizes the significant advantages of our rhCollagen.

Our Market Opportunity

Our rhCollagen represents a platform for the development of products addressing significant opportunities in multiple markets. We are initially focused on the regenerative medical and aesthetics market, aiming to become a global leader in these markets. We are developing, together with our development partner, AbbVie, a dermal and soft tissue fillers. Per the AbbVie Development Agreement, we have the potential to receive additional milestones payments, as well as receive meaningful royalties on product sales. See "Item 4.B. Business Overview—Our Products and Product Candidates".

We are developing a 3D-bioprinted breast implants, which are developed to regenerate breast tissue and thus may provide a revolutionary alternative for aesthetic and reconstructive procedures. In December 2023 we initiated a pre-clinical trial to evaluate commercial-size, 3D-bioprinted, regenerative breast implants.

We see a significant opportunity to use our rhCollagen platform to develop products to address additional indications in these markets as well as in new markets, including cardiovascular, orthobiologics, and ophthalmic markets. We believe that the potential addressable market opportunity for products using our rhCollagen and 3D-bioprinting technology is even greater than the market size served by currently available collagen-based products, mainly due to continued unmet medical needs and the utilization of 3D-bioprinting technology for tissue and organ manufacturing.

Regenerative Medicine and Aesthetic Markets

Dermal fillers are gaining popularity all across the globe due to increasing trend of using anti-aging treatments, growing aging population, demand to look younger and the use of social media. According to the American Society of Plastic Surgeons, comparing the 2023 procedural statistics to 2022, cosmetic surgery procedures have grown by 5%. Minimally invasive procedures gained traction throughout 2023, offering quicker recovery and almost instant results. More and more companies are in the search for safer and longer lasting fillers.

Broadly, facial fillers can be divided into four categories: autologous fat, collagens, hyaluronic acid, and synthetic fillers (e.g., Calcium hydroxylapatite, Polylactic acid). According to Global Market Insights Inc., in 2022, hyaluronic acid comprised the largest category of the dermal filler market, with approximately 55% market revenue share. In addition, according to the American Society of Plastic Surgeons, hyaluronic acid injectable fillers were ranked second in popularity among the top Cosmetic Minimally Invasive Procedures for 2022.

According to Allied Market Research report, titled, "Dermal Filler Market", global dermal filler market size accounted over $6.3 billion in 2023 and is estimated to grow at 10.3% to reach $16.8 billion by 2033.

Our regenerative breast implants aim to address an estimated $3.0 billion global breast implant market which is expected to reach $4.1 billion by 2033. Additionally, breast reconstruction and augmentation procedures represent the second most common plastic surgery procedure performed worldwide today. The most common breast augmentation or reconstruction procedures today are based on synthetic silicone breast implantations, an artificial substitution for natural regenerated tissue with risks of complications.

Currently, to our knowledge, there are no commercial products that allow regeneration of soft tissues such as the breast. In the U.S. alone, hundreds of thousands of people per year experience adverse events that range from autoimmune symptoms to the very serious breast implant-associated anaplastic large cell lymphoma (BIA-ALCL). CollPlant's breast implants that are comprised of the Company's proprietary plant-derived rhCollagen and other biomaterials, are expected to regenerate breast tissue without eliciting immune response, and thus may provide a revolutionary alternative for aesthetic and reconstructive procedures, including postmastectomy for cancer patients.

BioInk for 3D printing of tissues & organs

Regenerative medicine and tissue engineering have seen unprecedented growth in the past decade, driving the field of artificial tissue models towards a revolution in future medicine. Progress has been achieved through the development of innovative biomanufacturing strategies to pattern and assemble cells and extracellular matrix, or ECM, in three dimensions to create functional tissue constructs. Bioprinting has emerged as a promising 3D biomanufacturing technology, enabling precise control over spatial and temporal distribution of cells and ECM. Bioprinting technology can be used to engineer artificial tissues and organs by producing scaffolds with controlled spatial heterogeneity of physical properties, cellular composition, and ECM organization. This innovative approach is increasingly utilized in biomedicine, and has potential to create artificial functional constructs for drug screening and toxicology research, as well as tissue and organ transplantation.

Grand View Research Inc. estimates that the global 3D bioprinting market size was valued at $2.0 billion in 2022 and that the global market is expected to grow at a compound annual growth rate (CAGR) of 12.5% from 2023 to 2030. The growth of the global market is largely driven by increasing large demand of tissues and organs for transplantation and the innovations and advancements in technology for 3D bioprinting. A large number of people across the globe are waiting for an organ or tissue transplant, due to the large gap in demand for organ transplants and donors. This has created traction in the 3D bioprinting industry for developing live tissues and organs. Different companies along with academic institutes and laboratories are investing capital for 3D bioprinting research and development. Some of the other factors driving the growth of the global market include increasing research and development activities and increasing compliance for 3D bioprinting in drug discovery processes. Growing stem cell research and increasing adoption of 3D bioprinting in cosmetic industry are expected to create ample growth opportunities for the global market.

Orthopedic and wound care

Orthobiologics Market

An aging population, active demographics, innovative technology, and emerging geographic areas are expected to continue to drive growth in the global orthopedic market. Top market segments within orthopedics include reconstructive devices, such as joint replacements; spinal implants and instruments, used to treat joint pain; fracture repair, including the use of plates and screws; and arthroscopy and soft tissue repair, primarily for sports and movement related injuries.

Chronic complex musculoskeletal injuries that are slow to heal pose challenges to physicians and patients alike. Orthobiologics use cell-based therapies and biomaterials to help injuries heal more rapidly with a superior outcome. These products are made from substances that are naturally found in the body, which dynamically interact with the musculoskeletal system to facilitate the healing of bone, cartilage, meniscus, tendons, and ligaments affected by disease or injury. Orthobiologics products are spread across all segments of the larger orthopedic market, generating much of the growth within orthopedics. According to Fortune Business Insights, the global orthobiologics market size was valued at $8.36 billion in 2022 and is projected to grow $8.77 billion in 2023 to $12.78 billion by 2030, exhibiting a CAGR of 5.5% during 2023-2030.

Advanced Wound Care Market

The global market for wound care encompasses traditional dressings and bandages, as well as advanced wound care products such as bioengineered skin and skin substitutes and wound care growth factors. Over the past 30 years, there has been a shift from traditional wound dressings towards advanced therapies that aim to optimize the wound healing environment. Advanced wound care is composed of biocompatible products that are intended to actively promote wound healing by interacting either directly or indirectly with wound tissues. Attempts to reduce the duration of hospital stays in order to limit healthcare costs and the goal of enhancing therapeutic outcomes are driving the demand for advanced wound care and closure products. One of the primary market drivers for advanced wound care products is the increasing incidence of chronic wounds, which are on the rise due to an aging population and a sharp rise in the incidence of diabetes and obesity worldwide. Both advanced age and chronic medical conditions are associated with a slower healing process, and all phases of wound healing are affected. The inflammatory response is decreased or delayed, as is the proliferative response.

The global advanced wound care market in terms of revenue was estimated to be worth $11.2 billion in 2022 and is poised to reach $17.7 billion by 2027, growing at a CAGR of 9.4% from 2022 to 2027, according to Markets And Markets. The three major market segments are device-based wound care, comprised of negative-pressure wound therapy and hydrosurgery systems; moist wound care, comprised of dressings that create and maintain a moist environment; and biologics, comprised of bioactive technologies that provide new approaches to debridement and dermal repair and regeneration.

Our Strategy

All of our activities are driven by our goal to become the global market leader in regenerative and aesthetic medicine. As a disruptive technology company, we are facing the need to identify new markets opportunities and establish unique business models for revenue generation. Our value creation is based on our ability to develop and sell our product candidates, our sales of rhCollagen based products to our partners and selected customers, milestone payments and royalties on future sales of our partners. Our business model includes:

1. In-house development of aesthetic products and biofabricated scaffolds and tissues. Our current product pipeline addresses a multi-billion-dollar market.

2. In-licensing of our rhCollagen technology, and/or sales of rhCollagen and rhCollagen-based bioinks formulations, that constitute the ideal building blocks for regenerative medicine applications.

3. Co-development of more complex tissues and organs with tire-1 partners as well as collaborations with recognized universities and research organizations.

We intend to continue to develop additional products, both independently and with strategic collaborators, initially in 3D-bioprinting of tissues and organs, and medical aesthetics markets and subsequently in other high value markets, based on our rhCollagen. We believe the market-leading characteristics of our rhCollagen will create attractive collaboration opportunities for our products, and we intend to selectively establish collaborations and strategic partnerships with respect to our current and future products in order to accelerate their development and commercialization. We established a collaboration with Allergan aesthetics, an AbbVie company and we intend to engage with similar well-established companies whose distribution networks are deeply entrenched. We remain engaged in partnering dialogs with several industry leaders and academic institutions interested in our rhCollagen technology, biomaterials knowhow, and expertise in 3D-bioprinting, to develop therapeutics, medical and aesthetics products. Our product pipeline and our research and development program are expected to yield new products in the coming years.

Our rhCollagen is a platform technology which can be utilized in a broad range of therapeutic, aesthetic, and other medical applications, and in particular in emerging industries such as 3D-bioprinting which we believe cannot be adequately addressed with currently available collagen technologies. We believe our platform technology, and the knowledge and expertise we have gained will enable the development, either independently or with collaborators, of differentiated products in multiple industries with a short time to market.

Our Products and Product Candidates

Dermal Filler and Soft Tissue Fillers

In February 2021, we entered into the AbbVie Development Agreement with Allergan, an AbbVie company, pursuant to which we and AbbVie are collaborating in the development and commercialization of dermal and soft tissue filler products for the medical aesthetics market, using our rhCollagen technology in combination with AbbVie's technology. In February 2025, we announced the achievement of a development milestone with respect to this product candidate, which, according to the AbbVie Development Agreement, triggered a $2 million payment from AbbVie to us. This milestone achievement follows our announcement in June 2023 regarding another achievement which triggered a $10 million payment from AbbVie to us. The dermal filler product candidate is currently in the clinical phase. AbbVie is collecting data and conducting a review of interim results from the first cohort of patients enrolled under the trials initiated in 2023 and next steps for the program are to be determined by AbbVie upon concluding their assessment. The trials are designed, planned, and executed by AbbVie.

Pursuant to the AbbVie Development Agreement, we granted to AbbVie and its affiliates, worldwide exclusive rights to use our rhCollagen for the production and commercialization of dermal and soft tissue filler products, or the Exclusive Products.

Pursuant to the AbbVie Development Agreement, we successfully developed an aseptic process for sterile rhCollagen that meets certain specifications as set forth in the Development Agreement. In addition, the Development Agreement provides that later on, we and AbbVie will enter into a supply agreement whereby we will manufacture and supply AbbVie with rhCollagen, at a pre-agreed price, to be used solely for the development and manufacture of the Exclusive Products.

The AbbVie Development Agreement provides that with respect to the Exclusive Products we shall be entitled to receive up to $50 million comprised of an upfront cash payment of $14 million, which was paid in February 2021, and up to $36 million in proceeds upon the achievement of certain development, clinical trial, regulatory and commercial sale milestones, of which $10 million and $2 million were paid in July 2023 and in February 2025, respectively, following the achievement of a milestones with respect to the clinical-phase dermal and soft tissue filler product candidate. In addition, CollPlant shall be entitled to a fixed-fee royalty payment (subject to certain adjustments) for each product commercially sold during the applicable royalty term as well as a fee for the supply of rhCollagen to AbbVie.

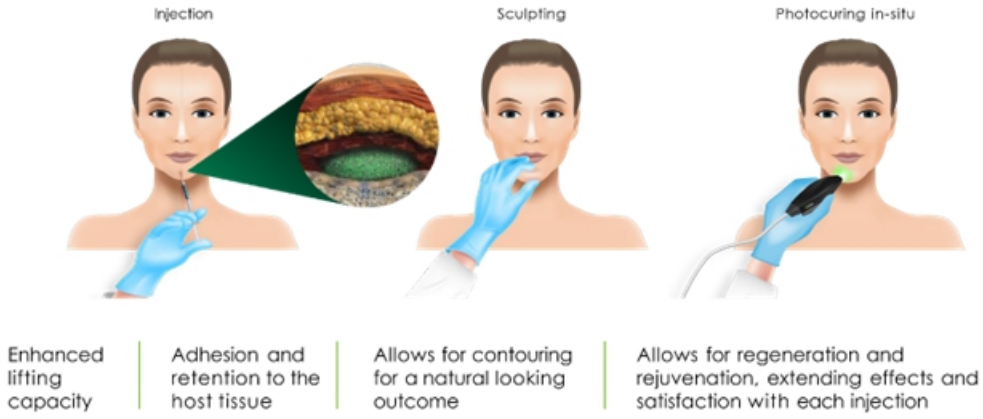
Further, pursuant to the AbbVie Development Agreement, we granted to AbbVie and its affiliates a right of first negotiation to enter into a definitive agreement to obtain exclusive, worldwide rights to the use of our rhCollagen for the commercialization and sale of an injectable breast implant product and for a photocurable dermal filler product. AbbVie did not pursue its right to first negotiation to enter into a definitive agreement to obtain exclusive, worldwide rights to the use of CollPlant rhCollagen for the commercialization and sale of a photocurable dermal filler product under the AbbVie Development Agreement and no longer has rights for this product candidate. Under the AbbVie Development Agreement, AbbVie continues to have a right of first negotiation option to the injectable breast implant candidate under development using CollPlant rhCollagen.

Unless earlier terminated, the AbbVie Development Agreement will continue in effect on a product-by-product and country-by-country basis until the later of (i) the expiration, invalidation or abandonment of the last CollPlant patent covering a product in a particular country, and (ii) 10 years from the first commercial sale of such product in such country. Following expiration (unless earlier terminated), the rights granted to AbbVie in the AbbVie Development Agreement will continue on a non-exclusive, fully paid-up, royalty-free, perpetual and irrevocable basis. The Development Agreement may be terminated early by either party for material breach or bankruptcy. In addition, AbbVie may terminate the AbbVie Development Agreement at any time immediately upon written notice to CollPlant if AbbVie reasonably believes that it is not advisable for AbbVie to continue to develop or commercialize the Exclusive Products under the AbbVie Development Agreement as a result of a perceived serious safety issue regarding the use of any Exclusive Product or upon 60 days' written notice, for any or no reason, with respect to its rights under the Agreement on an Exclusive Product-by-Exclusive Product or country-by-country basis.

Skin rejuvenation procedures are increasing in popularity, especially nonsurgical treatments such as dermal filler injections. Hyaluronic acid is a water-retaining molecule widely used for dermal filling, but lacks the ability to promote cell proliferation and tissue regeneration. This results in a limited-lasting effect.

A photocurable version of our tissue regenerating rhCollagen, serves as the basis for a new dermal filler product line now in development. We are developing a photocurable regenerative filler comprised of rhCollagen and other substances which is intended to provide several revolutionary effects: lifting, sculpturing ability, retention to the host tissue, and tissue regeneration.

rhCollagen-based Photocurable regenerative dermal filler key attributes:



The photocurable regenerative dermal filler is intended for injection in a semiliquid phase and hardened in-situ post injection by light illumination through the skin. Utilization of photocuring technology is expected to ease the injection process, particularly in subcutaneous and supraperiosteal applications. As the product degrades, a newly formed tissue is expected to regenerate and take its place.

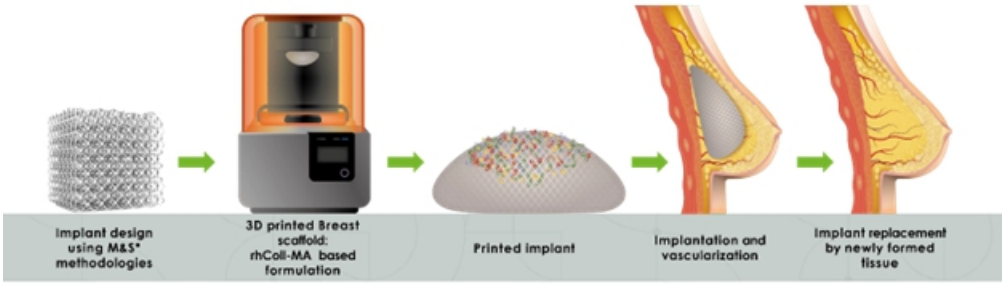
In early 2023 we completed a 12-month preclinical study, demonstrating superior tissue regeneration, lifting capacity and volume retention when compared to a commercial standard.

3D-Bioprinted Breast implants

Current breast reconstruction in the market is based on synthetic breast implantation and free flap surgery/autologous fat tissue transfer, all of which replace tissue rather than regenerate it. Breast augmentation and reconstruction through silicone implants, which are among the most popular surgical procedures, are associated with high risk for adverse events.

Our implants in development are bioprinted and loaded with compositions that are based on rhCollagen, and other biomaterials. These implants are intended to promote tissue regeneration and degrade in synchronization with the development of a natural breast tissue.

The following diagram demonstrate the phases of breast implant product candidate production and implementation.



In January 2023, we successfully completed a large-animal study for our 3D bioprinted regenerative breast implants with full achievement of study objectives, demonstrating tissue regeneration which included the formation of maturing connective tissue and neovascular networks. The histological analysis of the implants demonstrated progressive stages of tissue regeneration after three months, as indicated by the formation of maturing connective tissues and neovascular networks. The development of native tissue was synchronized with the degradation process of the implant, which was consistent with the desired outcome observed during the trial. There was also no indication of adverse reaction noted within the implants and the surrounding tissue.

In December 2023, we initiated a pre-clinical trial to evaluate commercial-size, 3D-bioprinted, regenerative breast implants. The primary goal of this study is to obtain data which would than support the optimization of the implant design and imply this design to a pivotal large-animal study that is intended to be the subject of discussion with the FDA.

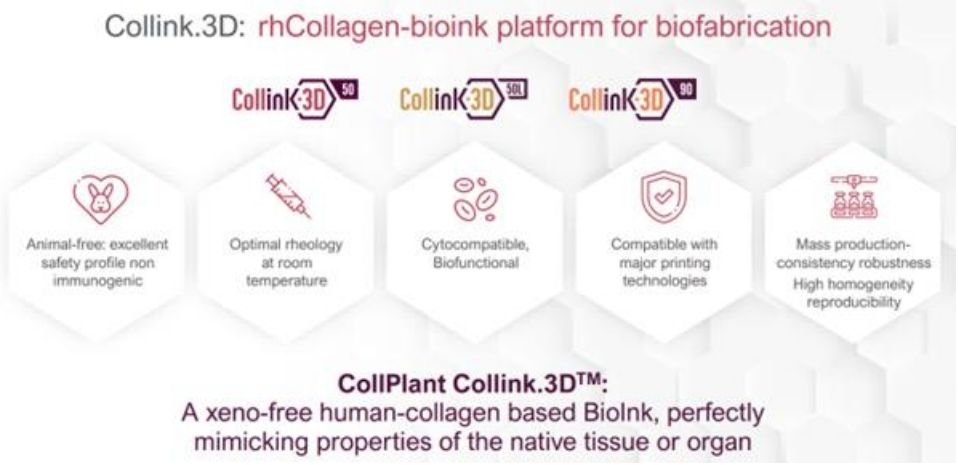
In August 2024, we launched this preclinical study with two arms, where the surgical protocol was refined to include implantation through a small incision while preventing implant displacement or inversion. Analysis of MRI and ultrasound data conducted in 2025 and 2024 confirmed tissue integration and vascularization, offering valuable diagnostic tools for future clinical applications. At six months post-implantation, one study arm has shown promising outcomes, with the implant demonstrating vascularization and rapid tissue ingrowth within the clinical-sized implant. No complications, such as capsule formation, calcifications, and local tissue reactions were observed. Additionally, volume retention and mechanical properties were maintained in the successful study arm. Following this study, we plan to continue to optimize the regenerative breast implants to ensure longevity and re-modelling of the neo-tissue.

In addition, we were in the initial stages of developing injectable breast implants, and an RTM for use in breast reconstruction procedures in combination with an implant. However, we decided to temporarily defer the development of both these products in order to concentrate our efforts on advancing the development of our 3D-bioprinted regenerative breast implants. We will consider resuming the development of both the injectable breast implants and RTM based on our 3D-bioprinted breast implant program progress.

Bioink for 3D printing of tissues & organs

3D-bioprinting is being applied to the field of regenerative medicine to address the need for complex scaffolds, tissues, and organs that are suitable for transplantation. We have developed rhCollagen-based bioinks that are optimized and provides an ideal building block for the three-dimensional bioprinting of tissues and organs.

For that purpose, rhCollagen was modified chemically to adapt the biological molecules for printing such that bioinks keep a controlled fluidity during printing and cure to form hydrogels when irradiated by certain light sources ranging from UV to visible light. The unique viscosity and shear thinning properties of the modified rhCollagen enable the formulation of bioinks that are suitable for different printing technologies including extrusion, ink-jet, Laser Induced Forward Transfer and Stereolithography. The control of chemical modification in combination with illumination energy allows tight control of the physical properties of the resulting scaffolds to match natural tissue properties, from stiff cartilage to soft adipose. bioinks formulated from rhCollagen were evaluated with all major currently available printing technologies and exhibited the required physical properties and excellent support for cells including a series of primary and differentiated human cells.



CollPlant's bioink based on rhCollagen – building block for tissue and organ manufacturing.

We believe our bioink offers ideal characteristics for 3D bioprinting, including:

- Biocompatibility—supports cell viability and promotes proliferation (e.g. endothelial cells, fibroblasts, keratinocytes, MSCs)
- Potential safety—has not shown to promote allergic and other tissue reactions
- Optimized viscosity and gelation kinetics—printability and compatibility with multiple printing technologies
- Curing with a range of light sources based on specific requirements
- Controlled degradation profile
- Controlled rheological properties (e.g. viscosity)
- Shear thinning properties – compatible with inkjet technology
- Convenient handling at broad range of temperatures and pH (e.g., maintains liquid properties at RT and above –no gelation)
- Compatible with different photoinitiators to cover the spectrum of 280-500nm
- Customized physical properties of the printed constructs that are compatible with natural tissues

In 2021 we announced the commercial launch of our rhCollagen-based bioink platform, by launching our first commercial bioink, Collink.3D™ 50 for use in 3D-bioprinting. Collink.3D™ 50, our first commercially available rhCollagen-based bioink product that was designed to allow the scalable and reproduceable biofabrication of scaffolds, tissues and organ transplants.

In November 2022, we launched Collink.3D™ 90, an rhCollagen-based bioink solution for use in a variety of 3D bioprinting applications, offering increased mechanical properties to address additional printing requirements of soft and hard tissues.

In January 2023, we launched Collink.3D™ 50L in powder form, which is our first bioink available in powder form and provides enhanced operational flexibility to support a wide range of 3D-bioprinting applications, including drug discovery, drug screening, tissue testing as well as the development of transplantable tissues and organs.

Made entirely from human-derived collagen, Collink.3D bioinks enables the production of scaffolds that accurately mimic the physical properties of human tissues and organs, with improved bio-functionality, safety and reproducibility.

Orthopedic and wound healing

VergenixSTR—Tendinopathy Treatment

VergenixSTR is a soft tissue repair matrix that combines cross-linked rhCollagen with PRP, a concentrated blood plasma that contains high levels of platelets, a critical component of the healing process. Platelets contain growth factors that are responsible for stimulating tissue generation and repair, including soft tissue repair, bone regeneration, development of new blood vessels, and stimulation of the wound healing process. VergenixSTR serves as a scaffold to support cell proliferation and the release of growth factors. The product is injected into the affected area and forms a viscous gel matrix which serves as a temporary reservoir for PRP in the vicinity of a tendon injury site, holding the platelet concentrate in place at the injured area. The matrix formed has the capabilities to activate the platelets in PRP, thereby releasing growth factors in a controlled manner and controlled biodegradation time, enabling optimal healing.

VergenixSTR is intended for the treatment of tendinopathy by promoting healing and repair of tendon injuries in a variety of tendons including the elbow tendon (for treatment of "tennis elbow"), rotator cuffs, patellar tendons, Achilles tendon, and hand tendon.

We estimate the size of the target market for VergenixSTR for treating tendinopathy is three million procedures per year, or approximately $2.0 billion. While our initial focus for VergenixSTR is in tendinopathy, VergenixSTR may be applicable to other soft tissue indications such as tendon rupture, meniscus tear, and cartilage repair, as well as in the aesthetic market.

Globally, the aging population is playing a major role in increasing the incidence of sports injuries as the reduced flexibility and mobility associated with aging can make the body more prone to injury.

We completed a 40 patient open label, single arm, and multi-center clinical trial of VergenixSTR at hospitals in Israel which demonstrated the safety and evaluated the performance of VergenixSTR in patients suffering from tennis elbow or *lateral epicondylitis*. Tennis elbow is an inflammation of the tendons that join the forearm muscles on the outside of the elbow. The trial, which commenced in January 2015, initially enrolled 20 patients and was expanded to enroll an additional 20 patients. Patients enrolled in the trial received a one-time injection of VergenixSTR and monitored for the level of pain, tendon healing, and recovery of hand movement at three and six months after treatment.

In August 2016, we announced final results. At the three-month and six-month follow ups, patients treated with VergenixSTR reported an average 51% and 59% reduction in pain and improvement in motion, respectively, as measured by score improvement over the baseline on the Patient-Rated Tennis Elbow Evaluation, or PRTEE, questionnaire. The PRTEE questionnaire is designed to measure reduction in pain and recovery of motion for patients with tennis elbow. Furthermore, at three-month and six-month follow ups, 74% and 86%, respectively, of patients treated with VergenixSTR showed at least a 25% reduction in pain and improvement in motion as measured by PRTEE. In contrast, a study of standard-of-care tennis elbow therapies published in 2010 in the American Journal of Sports Medicine, or AJSM, reported that, at three and six months, 48% and 36%, respectively, of steroid patients showed at least a 25% reduction in pain and improvement in motion as measured by PRTEE. Also at the three-month and six-month follow ups, 62% and 64%, respectively, of patients treated with VergenixSTR showed at least a 50% reduction in pain and improvement in motion as measured by PRTEE, whereas the 2010 AJSM study showed 33% and 17% reductions at three and six months, respectively, for this same measurement.

In October 2016, we received CE marking certification for VergenixSTR. In November 2016, we entered into an exclusive distribution agreement with Arthrex GmbH, for VergenixSTR and sales in Europe commenced in the fourth quarter of 2016. In March 2018, Arthrex announced results of ACP Tendo, a product for treatment of tendinopathy combining our Vergenix®STR and Arthrex's platelet rich plasma extraction kit, in a European case series. The safety and performance of ACP Tendo was evaluated for the treatment of tendinopathy in 24 patients in 9 different European locations. The indications included injuries in rotator cuff, Achilles tendon, peroneal tendon, tibialis tendon and common extensor tendon. In all treatment groups, patient-recorded-pain decreased after 2 weeks and continued along this trend up to the last follow-up at 6 months. Specifically for rotator cuff and common extensor tendon groups, the functionality was increased over the study period, almost achieving pre-symptom levels after 6 months.

VergenixFG—Wound Filler

VergenixFG is an advanced wound care product based on our rhCollagen. In the European Union, VergenixFG is intended for the treatment of deep surgical incisions and deep wounds, including diabetic ulcers, venous and pressure ulcers, burns, bedsores, and other chronic wounds that are difficult to heal. VergenixFG is designed to be easy to use and to be administrated through a cannula by a doctor or nurse. The VergenixFG formulation provides a scaffold of pure human collagen, an important characteristic in promoting the closure of wounds, that fills the wound bed and is engineered to create maximal contact with the surrounding tissue, which is believed to enhance healing. VergenixFG provides complete coverage of the wound site, facilitates wound closure through an engineered synchronization between scaffold degradation and growth of new tissue, and offers a non-allergenic and pathogen-free scaffold for safe and efficacious wound care therapy. Other flowable gel products are available on the market, but they are based on tissue-derived collagen.

Our initial market for VergenixFG in Europe is chronic wounds, which includes diabetic foot ulcers, venous ulcers, and pressure ulcers.

The population prevalence of chronic wounds is 2.21/1000 people, which equates to 1 million out of the 447 million inhabitants of the EU 27 in 2021.

We have completed an open label, single arm, and multi-center registration trial of VergenixFG of 20 patients in Israel to demonstrate safety and to evaluate the performance of VergenixFG in patients with hard-to-heal chronic wounds of the lower limbs. Patients enrolled in the trial, received a single treatment of VergenixFG followed by a four-week follow up. Product performance was examined according to several measures, the main one being the percentage of wound closure achieved. The results were published in February 2019 in Wounds, a peer-reviewed journal focusing on wound care and wound research. The paper, titled, "A Novel Recombinant Human Collagen-based Flowable Matrix for Chronic Lower Limb Wound Management: First Results of a Clinical Trial," presents data from a previously reported independent study conducted by physicians at several wound care medical clinics and hospitals in Israel. Four weeks following treatment, nine wounds closed completely, fifteen wounds exhibited a greater than 70% closure, and the median wound area reduction was 94%. Only one patient failed to respond to treatment. All patients in the study reported a 50% reduction in pain. Further, no significant device-related adverse events were reported throughout the study.

In February 2016, we received CE marketing certification for VergenixFG. Since then we have entered into distribution agreements for the distribution of VergenixFG in several countries in Europe and Asia. We currently do not intend to pursue an FDA regulatory pathway to market for VergenixFG.

In an investigator initiated study, 24 adults with diabetes admitted to the inpatient clinic of the University Hospital in Pisa, Italy between March and July 2017 were randomized to receive VergenixFG plus standard treatment (12 patients) or standard treatment (12 patients). They were evaluated weekly for 6 months or until complete healing had occurred. The group that received VergenixFG had a significantly higher healing rate (83.3% versus 58.3%) and shorter healing time (64±4 days versus 90±11 days) than the group receiving standard treatment. It was concluded that the addition of VergenixFG to standard treatment increased healing rate and shortened healing time in patients with post-surgical diabetic foot wounds. The study was published by Lacopi E et al in The Diabetic Foot Journal, Vol 23 No 2 2020.

Technology

Our rhCollagen is based upon research conducted by our founder and Chief Scientist, Prof. Oded Shoseyov. We believe our technology is the only viable technology available for the production of recombinant type I human collagen, the most abundant collagen in the human body.

The production of our rhCollagen begins with the creation of genetically engineered cultures that are transferred to selected greenhouses across Israel and continues with the harvesting of tobacco leaves and the processing of such leaves to an extract which then undergoes purification until the completion of the rhCollagen.

Five human genes encoding heterotrimeric type I collagen are introduced into tobacco plants. The three protein chains that make up type I collagen—two α1 protein chains and one α2 protein chain—are encoded by two genes. The other three genes encode the human prolyl-4-hydroxylase (P4Hα and P4Hβ) as well as lysyl hydroxylase 3 (LH3) enzymes. These enzymes are responsible for key post-translational modifications of collagen, and plants co-expressing all five of these vacuole-targeted genes generate intact procollagen. The plants are grown in a greenhouse under strict growing protocols and mature leaves are transported to a protein extraction facility. Upon extraction, pro-collagen is enzymatically converted to atelocollagen using a plant-derived protease. The protein is purified to homogeneity through a cost-effective industrial process taking advantage of collagen's unique properties that make it soluble at a very low pH.

rhCollagen forms thermally stable triple helix structures which readily fibrillate at natural pH and low sodium chloride concentrations, making it ideal for use in the manufacture of products for tissue repair in the human body. Binding of integrins (transmembrane receptors) presented by the cells to a specific 3D structure on type I collagen fibrils requires a perfect triple helix. This binding is essential for binding and proliferation of cells on tissue repair scaffolds. In a study published in the *Journal of Biomedical Materials Research Part B: Applied Biomaterials*, rhCollagen was compared with acid-solubilized collagen from bovine dermis and pepsin-solubilized collagen from human fibroblast cell culture. Tested samples of the tissue-derived collagens had random fibrillar organization, whereas rhCollagen membranes showed far greater regional fibril alignment and transparency. RhCollagen membranes also showed better thermal stability compared with the tissue-derived collagens. The authors concluded that cross-linked rhCollagen membranes had a superior combination of desirable properties, namely higher transparency, higher thermal and tensile strengths, and adequate hydration.

We have selected tobacco as the medium for production of rhCollagen due to certain attributes of the tobacco plant that provide us with a number of advantages:

- The genetic structure of tobacco is well understood and therefore can be effectively manipulated.
- We can monitor the effect of weather conditions on the accumulation of proteins in the plants, which allows us to make optimal use of the growing area. We control the growing process in order to maximize yields.
- Because tobacco is not part of the food chain, there are no concerns about cross-contamination of the food supply that could result from genetically modified plants, which eases the regulatory burden.
- Tobacco plants may be grown in very large volumes and its growth time until reaching the desired maturity is relatively short (about eight weeks).

Our Development Activities

Development History

Our rhCollagen was first developed as a collaboration among several commercial partners and the Hebrew University of Jerusalem, a major academic institution in Israel, under the direction of Professor Oded Shoseyov. Prof. Shoseyov is a faculty member at the Robert Smith Institute of Plant Science and Genetics at the Hebrew University of Jerusalem. The intellectual property was transferred to our wholly owned subsidiary, CollPlant Ltd.

As part of our regulatory strategy, we first developed and achieved a CE marking for a collagen-based non-invasive dressing, VergenixWD. We pursued a CE mark for this product as a predicate product for achieving in 2016 CE marking for our VergenixSTR and VergenixFG product in the European Union. To date, we have sold a few thousands kits of VergenixSTR and VergenixFG to distributors, and those kits have treated patients in several European countries.

In 2017, we created a division focused on development of collagen-based biological ink following the expansion of our research activities in the field of 3D biologic printing of organs and tissues. In the same year, we filed a provisional patent application for additive manufacturing using recombinant collagen-containing formulation. This patent application is in line with our strategy to expand the applications for rhCollagen for applications in the field of regenerative medicine. The subject provisional application has matured into granted patents in the U.S. (U.S. Patent No. 12,115,276), Japan, Australia, and has also been allowed in Japan. Applications are still pending in Europe, U.S., and Canada.

In 2018, we filed a provisional patent application for photocurable dermal fillers comprising rhCollagen and hyaluronic acid, for use in the aesthetics market. This application represents an integral part of our strategy to expand the uses for rhCollagen into new, high value markets. The subject provisional application has matured into granted patents in the U.S. (U.S. Patent No. 11,801,329 & U.S. Patent No. 12,186,449), Australia, Israel, Brazil, China, Europe and Japan. Applications are still pending in Europe, China, South Korea, U.S., Japan, Israel and Brazil. In Canada abandonment of this application arose from a patent office error. Correction and reinstatement has been requested and the patent office is expected to correct the error first in which case the application will be treated as never abandoned, and alternatively it is expected to reinstate to bring the application back into good standing.

In October 2018, we entered into a License, Development and Commercialization Agreement with LB, or the United License Agreement, pursuant to which we and LB collaborated in 3D bio-printing development of lungs for transplant in humans. On February 24, 2021, we received a notice of termination from LB of the United License Agreement, and the termination went effective on March 26, 2021. Under the United License Agreement we received an upfront cash payment of $5 million in November 2018 and a further $3 million in September 2020 following the exercise of an option under the United License Agreement.

In August 2019, we announced that we are developing 3D-bioprinted implants for regeneration of breast tissue and that we successfully produced first prototypes. The implants are comprised of our rhCollagen and additional materials and are intended to promote breast tissue regeneration. Eventually, the scaffold is designed to degrade and be replaced by newly grown natural breast tissue, that is free of any foreign material.

In January 2020, we announced that we became part of a new public-private Manufacturing USA initiative, or ARMI. Headquartered in Manchester, New Hampshire, ARMI brings together a consortium of over 150 partner organizations from industry, government, academia and the non-profit sector to develop next-generation manufacturing processes and technologies for cells, tissues and organs. We intend to contribute our expertise to advance the entire science and industry of bioengineering and manufacturing.

In December 2020, we entered into a product manufacturing and supply agreement with STEMCELL. As part of the agreement, we are selling our proprietary recombinant human Type I collagen (rhCollagen) to STEMCELL, which incorporates our product into cell culture media kits. The agreement follows the companies' established business relationship, which started in 2014 when STEMCELL began purchasing and incorporating our rhCollagen into some of its cell culture expansion and differentiation media kits. To date, hundreds of companies, as well as research and academic institutes, have used these kits for research and development projects.

In February 2021, we entered into the AbbVie Development Agreement, pursuant to which we and AbbVie agreed to collaborate in the development and commercialization of dermal and soft tissue filler products for the medical aesthetics market, using our rhCollagen technology and AbbVie's technology. In June 2023 and in February 2025, we announced the achievement of milestones with respect to the clinical-phase dermal filler product under the AbbVie Development Agreement, which triggered $10 million and $2 million payments, respectively, from AbbVie to us.

In November 2021, we launched Collink.3D 50 for use in 3D bioprinting. Collink.3D 50, our first commercially available rhCollagen-based bioink product is designed to allow the scalable and reproduceable biofabrication of scaffolds, tissues and organ transplants.

In November 2022 we launched Collink.3D 90, a rhCollagen-based bioink solution for use in a variety of 3D bioprinting applications, offering increased mechanical properties to address additional printing requirements of soft and hard tissues. Collink.3D 90 is complementary to our first commercial bioink, Collink.3D 50.

Also in November 2022, we entered into a license and research agreement with Tel Aviv University and Sheba Medical Center hospital, to co-develop a 'Gut-on-a-Chip' tissue model for drug discovery and high throughput screening of drugs. The model was intended to be used in personal medicine applications for the treatment of ulcerative colitis, an inflammatory bowel disease affecting millions of individuals worldwide. In November 2023, we elected to terminate our collaboration agreement with Tel Aviv University and Sheba Medical Center and continued to develop this program on our own. The program was later put on hold as we decided to focus our resources in advancing our 3D-bioprinted regenerative breast implants and dermal and soft tissue fillers programs. We intend to revisit the 'gut-on-a-chip' program and consider its initiation once resources become available.

In January 2023, we announced the successful results of our first large-animal study in 3D-bioprinted regenerative breast implants, which demonstrated progressive stages of tissue regeneration after three months, as highlighted by the formation of maturing connective tissue and neovascular networks within the implants, with no adverse events reported.

Also in January 2023, we launched Collink.3D 50L in powder form, which is our first bioink available in powder form and provides enhanced operational flexibility to support a wide range of 3D bioprinting applications, including drug discovery, drug screening, tissue testing as well as the development of transplantable tissues and organs.

In April 2023, we announced a joint development and commercialization agreement with Stratasys to collaborate on the development of a solution to bio-fabrication human tissues and organs, using Stratasys' P3 technology-based bioprinter and our rhCollagen-based bioinks.

In January 2024, we announced that we initiated a pre-clinical trial to evaluate commercial-size, 3D-bioprinted, regenerative breast implants. A primary goal of this study is to obtain data which would then support the optimization of the implant design and apply this design to a pivotal large-animal study that is intended to be the subject of discussions with the FDA.

In June 2024, we announced that we successfully printed for the first-time breast implants of 200 cc, which are commercial size. These implants were printed using CollPlant's proprietary rhCollagen bioinks. In addition, we announced additional, positive, interim preclinical data from ongoing large-animal studies, evaluating our regenerative breast implants. The data shows evidence of well-developed connective tissue containing blood vessels (i.e., neovascularization) within the implant. Progressing tissue ingrowth within the implant was also observed confirming tissue regeneration. An initial biodegradation process was observed, while preserving the original structure of the 3D breast implant. No adverse tissue reaction was observed, confirming the safety profile of this novel implant in development.

In August 2024, we and Stratasys announced the initiation of a pre-clinical study with CollPlant's 200cc commercial-sized implants printed on Stratasys' Origin 3D printer. We are expecting to have initial results from the study in the first half of 2025.

Future Development

To facilitate efficient development, our management holds regular research and development meetings where they prioritize development projects and determine future products. The prioritization process is based on several factors, including our business plan, commercial potential of the products, time to market, cost of development, feasibility of the project, regulatory pathway and our established strategic objectives.

We periodically examine the continued development of other collagen-based products that we have conceived. Each one of our current products or product candidates offers a platform to product derivatives that can address other indications and contribute to our pipeline and revenues.

Manufacturing, Supply, and Production

The majority of our product research and development work is carried out at our headquarters and research laboratories center in Weizmann Science Park in Rehovot, Israel. The agricultural research and development and production activities for our rhCollagen are carried out at our sites in Yessod Hama'ala and in Rehovot, Israel.

We work with subcontractors for growing the tobacco plant containing human collagen. This tobacco growth occurs year-round and is optimized to the climate conditions in order to achieve the maximum amount of the protein in the leaves. Each grower has the infrastructure that can be scaled-up to accommodate future demand without additional capital expenditures.

We produce the rhCollagen from the tobacco plants at our facilities in Yessod Hama'ala and Rehovot, Israel. We believe that we currently have the ability to produce sufficient quantities of quality recombinant type I human collagen to support our product development activities and sales until 2028. Our activities are focused on yield improvement, scale-up, and cost reduction.

In late 2021, we initiated a plan to upgrade our production site in Israel into a large-scale integrated facility, in order to accommodate expected future increase in demand. We will continue with the plan once there is a surge in demand and the necessary funds are secured for its execution.

While our upstream and downstream processes are quite robust and efficient, we continuously invest in further yield improvement and scalability, in order to reduce costs. In order to increase yield, we plan to increase biomass per growing area by using new genetic derivatives, improvement and optimization of growing techniques, and introduction of online controls. Our next-generation tobacco plants have been created through improved genetics and cross-breeding. In addition, increased growing areas will reduce overall cost per harvest.

We have an approved in-house purification capability. The purification facility includes clean rooms, logistics support areas, and dedicated production equipment to support the Company's production demand for the next few years. Under our current production techniques, we achieve a cost of goods that allow us to offer competitive pricing in the premium collagen-based products markets.

Sales, Marketing, and Distribution

We sell our bioinks and rhCollagen directly to our business partners, collaborators and selective customers. We anticipate that any products we develop in collaboration with a strategic partner or collaborator, such as dermal fillers which are based on our rhCollagen for the medical aesthetics, will be marketed by the partner's sales force,

We have been marketing and distributing VergenixSTR and VergenixFG in the European market with business partners since 2016. We also have two distributors for VergenixSTR in Europe and one in Southeast Asia. We continue exploring opportunities to distribute our Vergenix products in additional countries.

We have undertaken post marketing surveillance, or PMS, studies for both VergenixSTR and VergenixFG with our European key opinion leaders and physicians to generate additional clinical data that demonstrates the efficacy, safety and clinical benefit of these products. These PMS studies are intended to facilitate market adoption of our products in Europe, to confirm product safety and performance as well as to provide additional clinical evidence in support to regulatory filing and submission to other regulatory agencies in the future.

Our proprietary Vergenix products are marketed, and intended to be marketed, to physicians, hospitals, and clinics. We plan to expand the awareness of rhCollagen and our rhCollagen-based products to the end users through the publication of clinical trial data as well as marketing studies we may conduct, along with participation in academic and industry conferences. We will also market our rhCollagen to companies who are developing products using collagen and that do not compete with our primary end products. We anticipate entering into collaborations or partnerships with these companies where we would supply them with rhCollagen for use in their products in return for royalties.

Competition

We are not aware of any competitors that produce human collagen from plants or that produce recombinant type I human collagen. However, our industry is characterized by rapidly evolving technology and intense competition, and our rhCollagen-based products will compete with several alternatives, such as collagen that is produced from animals, human cadavers and synthetic products. Adequate protection of intellectual property, successful product development, adequate funding, and retention of skilled, experienced, and professional personnel are among the many factors critical to success in the pharmaceutical industry.

Generally, our competitors currently include large fully integrated companies, as well as academic research institutes and companies in various developmental stages that develop alternative sources and forms of collagen and tissue-derived products, who are using collagen that is extracted from animals and human cadavers.

The main competitors to our dermal/soft tissue fillers that are in development with AbbVie include Galderma, Merz Aesthetics, Sinclair and AbbVie.

The main competitors to our 3D bioprinted regenerative breast implants that are in development include the commercially available breast implants by Allergan, Inc., an AbbVie company, and Mentor Worldwide LLC, Johnson & Johnson company.

The primary competitors to our bioink are potential bio-material inks for 3D biological printing, based on tissue-derived collagens. Manufacturers of these products include, among others, BICO (formerly Cellink), Allevi (now part of 3D systems) and Humabiologics.

The main competitors to our photocurable dermal fillers that are in development include the main commercially available hyaluronic acid dermal filler brands by Galderma, Sinclair and Merz.

Our VergenixSTR product competes with companies that sell steroid injections and PRP kits, including, among others, Zimmer Biomet., Harvest Technologies Corporation, and Arteriocyte Medical Systems Inc.

The main competitors to our VergenixFG product are products based on tissue-derived collagens. Manufacturers of these products include, among others, Integra Lifesciences Corporation, Organogenesis, Wright Medical Technology Inc., Smith & Nephew, Molnlycke, Convatec, Coloplast, and Urgo.

Intellectual Property

Our success depends, in part, on our ability to protect our proprietary technology and intellectual property. We rely on a combination of patent, trade secret, and trademark laws in the United States and other jurisdictions to protect our intellectual property rights. In addition, we rely on proprietary processes and know-how, intellectual property licenses, and other contractual rights, including confidentiality and invention assignment agreements, to protect our intellectual property rights and develop and maintain our competitive position.

Patents

As of March 4, 2025, we have a global patent portfolio that is comprised of sixteen patent families. More than four dozen of the patent applications have been issued as patents or will issue soon, having been allowed by the relevant patent offices, of which six are European Patents validated in several member states. We have an exclusive ownership of fourteen issued patents in our patent portfolio that cover methods of producing collagen in plants and three issued patents that cover methods of processing recombinant collagen. These issued patents are expected to expire in 2025-2029. We have a pending patent family covering specific collagen producing plants based on their genetic arrangement. A patent for this family was granted in Japan, and is expected to provide patent protection for the collagen producing plants until 2039. Our patent portfolio also includes patent families that cover different uses of collagen including 3D Bioprinting, dermal fillers and soft tissue fillers and/or implants which, if granted, could provide patent protection for particular formulations and uses of the rhCollagen until 2038-2042.

In addition, our patent portfolio includes patents, some of which are jointly owned with Yissum Research Development Company of the Hebrew University of Jerusalem Ltd.

We are not aware of any impediments to the patent applications being granted in the United States or other jurisdictions. However, some of our patent applications may never issue as patents, and our issued patents and any that may issue in the future may be challenged, invalidated or circumvented.

Trademarks

We have registered the marks VERGENIX and COLLINK.3D in several countries and have pending applications for each.

Trade Secrets and Confidential Information

In addition to patented technology, we rely on our trade secrets and continuing technological innovations to develop and maintain our competitive position. In an effort to protect our trade secrets, we rely on, among other safeguards, confidentiality and invention assignment agreements to protect our proprietary technology, know-how and other intellectual property that may not be patentable or that we believe is best protected by means that do not require public disclosure. For example, we require our employees, consultants and advisors to execute confidentiality agreements in connection with their employment or consulting relationships with us and to disclose and assign to us inventions conceived in connection with their services to us whether they are later described and claimed in a patent application or kept as a trade secret. These agreements also provide that all confidential information developed or made known to the individual during the course of their relationship with us must be kept confidential, except in specified circumstances.

Materials Transfer Agreements

We periodically enter into materials transfer agreements with commercial organizations, medical institutions and research and development institutions to transfer materials and products developed by us. These agreements include provisions that are customary for such agreements concerning the permitted use of the transferred material and any results obtained using the material, confidentiality, the rights in the transferred materials and in the results of the research and/or development in which the materials are used, and the instructions concerning care and usage of the materials. These agreements may be used as a basis for further cooperation between us and the counterparties.

We may be unable to obtain, maintain, and protect the intellectual property rights necessary to conduct our business and may be subject to claims that we infringe or otherwise violate the intellectual property rights of others, which could materially harm our business. For a more comprehensive summary of the risks related to our intellectual property, see “Item 3.D. Risk Factors.”

Agreement with Yissum Research Development Company of the Hebrew University of Jerusalem Ltd. with respect to our rhCollagen

Under an agreement dated July 13, 2004 among Meytav—Technological Innovation Center Ltd., Yehuda Zafrir Fagin, Yissum, and Prof. Oded Shoseyov (our Chief Scientist), we carried out a research and development project to develop a process for the production of quality human collagen in plants and further developed the resulting products created by us, Professor Shoseyov and Zafrir, for commercial applications. Yissum and Professor Shoseyov have assigned all intellectual property rights developed by Professor Shoseyov and owned by them to us, including the intellectual property rights in connection with the development of the method for production of quality human collagen in plants.

Government Regulation

We are a developer of products which are subject to extensive regulation in the United States, the European Union and other jurisdictions. These regulations govern, among other things, the introduction of new products, the observance of certain standards with respect to the design, manufacture, testing, promotion and sales of the products, the maintenance of certain records, the ability to track devices, the reporting of potential product defects, the import and export of devices, and other matters.

In order to obtain marketing authorization in the United States, we and/or our partners would be subject to extensive regulation by the FDA and other federal, state, and local regulatory agencies. The Federal Food, Drug, and Cosmetic Act, or FD&C Act, the Public Health Service Act, or the PHS Act, and their implementing regulations set forth, among others, requirements for the research, testing, development, manufacture, quality control, safety, effectiveness, approval, labelling, storage, record keeping, reporting, distribution, import, export, advertising, and promotion of our products. A failure to comply with relevant requirements may lead to administrative, civil, or criminal sanctions. These sanctions could include the imposition by the FDA of a clinical hold or other suspension on clinical trials, refusal to approve pending marketing applications or supplements, withdrawal of approval, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties, or criminal prosecution.

Although the discussion below focuses on regulation in the United States, we and/or our partners anticipate seeking approval for the marketing of products in other countries which have their own regulatory requirements. Generally, our activities or those of our partners in other countries will be subject to regulations that are similar in nature and scope as that imposed in the United States such as medical device approval, quality system requirements, product data and certifications, although there can be important differences and the number and scope of these regulatory requirements are generally increasing.

We and/or our partners must obtain approval by comparable regulatory authorities of foreign countries outside of the European Union and the United States before we can commence clinical trials or marketing of our products in those countries. The approval process varies from country to country and the process may be longer or shorter than that required for FDA approval. In addition, the requirements governing the conduct of clinical trials, product licensing, pricing, and reimbursement vary greatly from country to country. In all cases, clinical trials must be conducted in accordance with the FDA's regulations, commonly referred to as good clinical practices, or GCPs, and the applicable regulatory requirements and ethical principles that have their origin in the Declaration of Helsinki.

Government regulation may delay or prevent testing or marketing of our products and impose costly procedures upon our activities. The testing and approval process, and the subsequent compliance with appropriate statutes and regulations, require substantial time, effort, and financial resources, and we cannot be certain that the FDA or any other regulatory agency will grant approvals for our products or any future product candidates on a timely basis or at all. The policies of the FDA or any other regulatory agency may change and additional governmental regulations may be enacted that could prevent or delay regulatory approval of our products or any future product candidates or approval of new indications or label changes. We cannot predict the likelihood, nature or extent of adverse governmental regulation that might arise from future legislative, judicial, or administrative action, either in the United States or abroad.

Approval by Health Authorities

The following is a summary review of the laws and regulations governing our operations or those of our partners. Our end products are medical and aesthetics products, and their marketing, once development is complete, is contingent upon approval of the health authorities in every country in which the products will be marketed:

Israel

Our operations are subject to permits from the Ministry of Health, or the MoH, on two levels:

- First, the registration of medical devices, importing and marketing the medical devices and accessories, and issuing the documentation necessary for the export of medical devices from Israel is governed by the Medical Devices Law, 5712 – 2012, or the Medical Devices Law. The Medical Devices Law sets forth obligations of registration of medical devices in Israel. Under the Medical Devices Law, medical devices may be manufactured and marketed in Israel only if they are first registered with the Medical Devices Department of the MOH, also referred to as the "AMAR", which manages a registry for medical devices.

- Second, pertaining to research and development. Clinical trials in humans are subject to the approval of the Helsinki Committee (an ethics committee) of the institution conducting the trial, which is governed by the Public Health Regulations (Trials in Human Beings), 1980, including all amendments until 1999, or the Trials in Human Subjects Regulations and are conducted in accordance with the Guidelines for Clinical Trials in Human Subjects issued by the MOH, or the Guideline**s**, and the guidelines of the Declaration of Helsinki, or any other approval required by the MOH. According to the Trials in Human Subjects Regulations and the Guidelines, the Helsinki Committee must plan and approve every experimental process that involves human beings. The institutional Helsinki Committee acts in the medical institution where the trial is performed and is the body that approves and supervises the entire trial process. In practice, the physician, who is the principal investigator, submits a trial protocol to the committee on behalf of the requesting party. The committee forwards its decisions regarding the requests for clinical trials that were approved by the committee to the manager of the medical institute and the manager has the authority to approve the requests, and in some cases the additional approval of the MOH will be required. According to the procedure for medical trials in human beings set forth by the MOH, the Helsinki Committee will not approve performance of a clinical trial, unless it is absolutely convinced that the following conditions, among others, are fulfilled: (i) the anticipated benefits for the participant in the clinical trial and to the requesting party to justify the risk and the inconvenience involved in the clinical trial to its participant; (ii) the available medical and scientific information justifies the performance of the requested clinical trial; (iii) the clinical trial is planned in a scientific manner that enables a solution to the tested question and is described in a clear, detailed, and precise manner in the protocol of the clinical trial, conforming with the Declaration of Helsinki; (iv) the risk to the participant in the clinical trial is as minimal as possible; (v) optimal monitoring and follow-up of the participant in the clinical trial; (vi) the initiator, the principal investigator and the medical institute are capable and undertake to allocate the resources required for adequate execution of the clinical trial, including qualified personnel and required equipment; and (vii) the nature of the commercial agreement with the principal investigator and the medical institute does not impair the adequate performance of the clinical trial.

All phases of clinical trials conducted in Israel must be conducted in accordance with the Trials in Human Subjects Regulations, including amendments and addenda thereto, the Guidelines, and the International Conference for Harmonized Tripartite Guideline for Good Clinical Practice. The Trials in Human Subjects Regulations and the Guidelines stipulate that a medical study on humans will only be approved after the Helsinki Committee at the hospital intending to perform the study has approved the medical study and notified the relevant hospital director in writing. In addition, certain clinical studies require the approval of the MOH. The relevant hospital director, and the MOH, if applicable, also must be satisfied that the study is not contrary to the Declaration of Helsinki or to other regulations.

In June 2017, we received AMAR approval for VergenixFG and started treating patients in Israel. In March 2018, we received AMAR approval for VergenixSTR.

United States

The regulatory process of obtaining product approvals and clearances can be onerous and costly. Foreign companies manufacturing medical devices intended for sale in the United States are required to meet the FDA's regulatory requirements. The FDA does not recognize the regulatory certification provided by governmental authorities of other countries.

Regulation of Combination Products

The FDA has specified a definition for the term "combination product," which includes: (1) a product comprised of two or more regulated components, e.g., drug/device, biologic/device, drug/biologic, or drug/device/biologic, which are physically, chemically, or otherwise combined or mixed and produced as a single entity; (2) two or more separate products packaged together in a single package or as a unit and comprised of drug and device products, device and biological products, or biological and drug products; (3) a drug, device, or biological product packaged separately that according to its investigational plan or proposed labeling is intended for use only with an approved individually specified drug, device, or biological product where both are required to achieve the intended use, indication, or effect and where, upon approval of the proposed product, the labeling of the approved product would need to be changed, e.g., to reflect a change in intended use, dosage form, strength, route of administration, or significant change in dose; or (4) any investigational drug, device, or biological product packaged separately that according to its proposed labeling is for use only with another individually specified investigational drug, device, or biological product where both are required to achieve the intended use, indication, or effect.

The FDA is divided into various "Centers" by product type such as the Center for Drug Evaluation and Research, or CDER, the Center for Biologics, Evaluation and Research, or CBER, or the Center for Devices and Radiological Health, or CDRH. Different Centers review drug, biologic, or device applications.

The FDA is charged with assigning a Center with primary jurisdiction, or a lead Center, for review of a combination product. That determination is based on the "primary mode of action," or PMOA, of the combination product. Thus, if the PMOA of a device-biologic combination product is attributable to the biologic product, CBER, which is responsible for premarket review of the biologic product, would have primary jurisdiction for the combination product.

The FDA has also established an Office of Combination Products to address issues surrounding combination products and provide more certainty to the regulatory review process. That office serves as a focal point for combination product issues for agency reviewers and industry. It is also responsible for developing guidance and regulations to clarify the regulation of combination products and for assignment of the FDA center that has primary jurisdiction for review of combination products where the jurisdiction is unclear or in dispute.

After formally establishing the PMOA through an applicant's Request for Designation, the Center that regulates that portion of the product that generates the PMOA becomes the lead evaluator. When evaluating an application, a lead Center may consult other centers but still retain complete reviewing authority, or it may collaborate with another Center, wherein the lead Center assigns concurrent review of a specific section of the application to another Center, delegating its review authority for that section.

Typically, the FDA requires a single marketing application submitted to the Center selected to be the lead evaluator, although the agency has the discretion to require separate applications to more than one Center. One reason to submit multiple evaluations is if the applicant wishes to receive some benefit that accrues only from approval under a particular type of application, like new drug product or orphan drug exclusivity. If multiple applications are submitted, each may be evaluated by a different lead Center. When submitting multiple applications, the applicant may be subject to the payment of two user fees, but a waiver of such fees may be obtained under certain limited circumstances.

The FDA may subject a combination product to two or more sets of legal authorities, e.g., drug/device, biologic/device, or drug/biologic drug, but it has the authority to deem one set of legal authorities sufficient. FDA's standard of review for a combination products application and the applicable legal authority or authorities will depend on a case-by-case basis evaluation of the scientific and technical issues and risk profile relevant to a combination product and its constituent parts. Because of the breadth and complexity of this analysis in each case, no single regulatory paradigm is appropriate for all combination products.

After receiving FDA approval or clearance, an approved or cleared product must comply with post-marketing safety reporting requirements applicable to the product based on the application type under which it received marketing authorization. In the case of current good manufacturing practices, or cGMP, the applicant may take one of two approaches: (1) complying with cGMP for each constituent part, or (2) a streamlined approach specific to combination products, subject to certain limitations.

In January 2019, the FDA responded to the Company's Pre-RFD regarding product classification and jurisdictional assessment. The FDA's OCP determined that VergenixSTR should be classified as a Combination Product, specifically a drug/biologic/device product, and should be assigned to the FDA's CBER. A Pre-RFD is FDA's preliminary, nonbinding assessment of (1) the regulatory identity or classification of a product as a drug, device, biological product, or combination product, and (2) which FDA Center (i.e., CBER, CDER, or CDRH) will have primary jurisdiction for the premarket review and regulation of the product. Therefore, this classification and jurisdictional assessment is subject to change. We currently do not intend to pursue a FDA regulatory pathway to market for VergenixSTR and VergenixFG. We nevertheless include a discussion of FDA's requirements for approval of, and ongoing, regulation for drugs, biologics, and medical devices below which are relevant to the end products that we are either developing internally or in collaboration with our partners.

Marketing Authorization for Drugs and Biologics in the U.S.

A new biologic must be approved by the FDA through the biologics license application, or BLA, process before it may be legally marketed in the U.S. A new drug must be approved by the FDA through the new drug application, or NDA, process before it may be legally marketed in the U.S.

The animal and other non-clinical data and the results of human clinical trials performed under an Investigational New Drug, or IND, application and under similar foreign applications will become part of the BLA or NDA.

In the U.S., the FDA regulates biologics under the Public Health Service Act, or PHS Act, and implementing regulations, and under the Federal Food, Drug, and Cosmetic Act, or FDCA, and implementing regulations, respectively. The U.S. regulates drugs under the FDCA. The process of obtaining regulatory approvals and the subsequent compliance with applicable federal, state, local, and foreign statutes and regulations require the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval may subject an applicant to administrative or judicial sanctions. These sanctions could include the FDA's refusal to approve pending applications, withdrawal of an approval, a clinical hold, warning letters, requesting product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement, or civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on us. The process required by the FDA before a drug or biologic may be marketed in the U.S. generally involves the following:

- completion of preclinical laboratory tests, animal studies and formulation studies according to Good Laboratory Practices, or GLP, or other applicable regulations;
- submission to the FDA of an IND which must become effective before human clinical trials may begin;
- approval by an IRB representing each clinical trial site before each clinical trial may be initiated;
- performance of adequate and well-controlled human clinical trials according to Good Clinical Practices, or GCP, to establish the safety and efficacy of the proposed biologic for its intended use;
- preparation and submission of a BLA or NDA to the FDA;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the drug is produced to assess compliance with current good manufacturing practice, or cGMP, to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity; and satisfactory completion of any FDA audits of the clinical study sites to assure compliance with GCP, and the integrity of clinical data in support of the BLA or NDA; and
- FDA review (which may include Advisory Panel review and approval) and approval of the BLA or NDA.

Once a biologic or drug product candidate is identified for development, it enters the preclinical testing stage. Preclinical tests include laboratory evaluations of product chemistry, toxicity and formulation, as well as animal studies. An IND sponsor must submit the results of the preclinical tests, together with manufacturing information and analytical data, to the FDA as part of the IND. The sponsor will also include a protocol detailing, among other things, the objectives of the first phase of the clinical trials, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated if the first phase lends itself to an efficacy evaluation. Some preclinical testing may continue even after the IND is submitted. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, places the clinical trial on a clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. Clinical holds also may be imposed by the FDA at any time before or during studies due to safety concerns or non-compliance.

All clinical trials must be conducted under the supervision of one or more qualified investigators in accordance with GCP regulations. They must be conducted under protocols detailing the objectives of the trial, dosing procedures, subject selection and exclusion criteria, and the safety and effectiveness criteria to be evaluated. Each protocol must be submitted to the FDA as part of the IND, and progress reports detailing the results of the clinical trials must be submitted at least annually. In addition, timely safety reports must be submitted to the FDA and the investigators for serious and unexpected adverse events. An IRB responsible for the research conducted at each institution participating in the clinical trial must review and approve each protocol before a clinical trial commences at that institution and must also approve the information regarding the trial and the consent form that must be provided to each trial subject or his or her legal representative, monitor the study until completed and otherwise comply with IRB regulations.

- *Phase I*: The product candidate is initially introduced into healthy human subjects and tested for safety, dosage tolerance, absorption, metabolism, distribution and excretion. In the case of some products for severe or life-threatening diseases, such as cancer, especially when the product may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing may be conducted in patients.

- *Phase II*: This phase involves studies in a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage.

- *Phase III*: Clinical trials are undertaken to further evaluate dosage, clinical efficacy and safety in an expanded patient population at geographically dispersed clinical study sites. These studies are intended to establish the overall risk-benefit ratio of the product candidate and provide, if appropriate, an adequate basis for product labeling.

Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of a biologic or drug and finalize a process for manufacturing the product in commercial and clinical quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate, and, among other things, the manufacturer must develop methods for testing the identity, strength, quality and purity of the final product. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life. Before approving a BLA or NDA, the FDA typically will inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in full compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. The PHS Act in particular emphasizes the importance of manufacturing control for products like biologics whose attributes cannot be precisely defined.

Manufacturers and others involved in the manufacture and distribution of products must also register their establishments with the FDA and certain state agencies. Both domestic and foreign manufacturing establishments must register and provide additional information to the FDA upon their initial participation in the manufacturing process. Any product manufactured by or imported from a facility that has not registered, whether foreign or domestic, is deemed misbranded under the FDCA.

Establishments may be subject to periodic unannounced inspections by government authorities to ensure compliance with cGMP and other laws. Manufacturers may have to provide, on request, electronic or physical records regarding their establishments. Delaying, denying, limiting, or refusing inspection by the FDA may lead to a product being deemed to be adulterated. Human clinical trials for biologics and drugs are typically conducted in three sequential phases that may overlap or be combined. If there are two independent modes of action, neither of which is subordinate to the other, the FDA makes a determination as to which center to assign the product based on consistency with other combination products raising similar types of safety and effectiveness questions or to the center with the most expertise in evaluating the most significant safety and effectiveness questions raised by the combination product.

Marketing Authorization for Medical Devices in the U.S.

In the United States, medical devices are regulated by the FDA as required under the FDCA. Unless an exemption applies or the product is a Class I device, a new medical device will require either a 510(k) clearance or approval of a Premarket Approval, or PMA, before it can be marketed in the United States. The information that must be submitted to the FDA in order to obtain clearance or approval to market a new medical device varies depending on how the medical device is classified by the FDA. Medical devices are classified into one of three classes on the basis of the controls deemed by the FDA to be necessary to reasonably ensure their safety and effectiveness. Class I devices, which are those that have the lowest level or risk associated with them, are subject to general controls, including labeling, premarket notification, and adherence to the QSR. Class II devices are subject to general controls and special controls, including performance standards. Class III devices, which have the highest level of risk associated with them, are subject to most of the previously identified requirements as well as to premarket approval. Most Class I devices and some Class II devices are exempt from the 510(k) requirement, although manufacturers of these devices are still subject to registration, listing, labeling and Quality System Requirements, or QSR.

A 510(k) premarket notification must demonstrate that the device in question is substantially equivalent to another legally marketed device, or predicate device, that likely did not require premarket approval. In evaluating the 510(k), the FDA will determine whether the device has the same intended use as the predicate device, and: (i)(a) has the same technological characteristics as the predicate device, or (b) has different technological characteristics; and (ii)(a) the data supporting the substantial equivalence contains information, including appropriate clinical or scientific data, if deemed necessary by the FDA, that demonstrates that the device is as safe and as effective as a legally marketed device, and (b) does not raise different questions of safety and effectiveness than the predicate device. Most 510(k)s do not require clinical data for clearance, but the FDA may request such data. If the FDA does not agree that the new device is substantially equivalent to the predicate device, the new device will be classified in Class III, and the manufacturer must submit a PMA.

The PMA process is more complex, costly, and time consuming than the 510(k) clearance procedure. A PMA must be supported by extensive data including, but not limited to, technical, preclinical, clinical, manufacturing, control, and labeling information to demonstrate to the FDA's satisfaction the safety and effectiveness of the device for its intended use. After a PMA is submitted, the FDA has 45 days to determine whether it is sufficiently complete to permit a substantive review, but this timeline may be delayed. If the PMA is complete, the FDA will file the PMA. The FDA is subject to performance goal review times for PMAs and may issue a decision letter as a first action on a PMA within 180 days of filing, but if it has questions, it will likely issue a first major deficiency letter within 150 days of filing. It may also refer the PMA to an FDA advisory panel for additional review and will conduct a preapproval inspection of the manufacturing facility to ensure compliance with the QSR, either of which could extend the 180-day response target. A PMA can take several years to complete, and there is no assurance that any submitted PMA will ever be approved. Even when approved, the FDA may limit the indication for which the medical device may be marketed. Changes to the device, including changes to its manufacturing process, may require the approval of a supplemental PMA.

If a medical device is determined to present a "significant risk," the manufacturer may not begin a clinical trial until it submits an investigational device exemption, or IDE, to the FDA and obtains approval of the IDE from the FDA. The IDE must be supported by appropriate data, such as animal and laboratory testing results, and include a proposed clinical protocol. The clinical trials must be conducted in accordance with applicable regulations, including but not limited to the FDA's IDE regulations and current good clinical practices. A clinical trial may be suspended by the FDA or the sponsor at any time for various reasons, including a belief that the risks to the study participants outweigh the benefits of participation in the trial. Even if a clinical trial is completed, the results may not demonstrate the safety and efficacy of a device or may be equivocal or otherwise not be sufficient to obtain approval. Medical devices, however, typically rely on one or a few pivotal studies rather than Phase I, II and III clinical trials

Clinical trials are subject to extensive monitoring, recordkeeping and reporting requirements. Clinical trials must be conducted under the oversight of an IRB for the relevant clinical trial sites and must comply with FDA regulations, including, but not limited to, those relating to good clinical practices. To conduct a clinical trial, we also are required to obtain the patient's informed consent in a form and substance that complies with both FDA requirements and state and federal privacy and human subject protection regulations.

The FDA, the IRB, or we could suspend a clinical trial at any time for various reasons, including a belief that the risks to study subjects outweigh the anticipated benefits or a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients. Clinical testing may not be completed successfully within any specified period, if at all. Even if a trial is completed, the results of clinical testing may not adequately demonstrate the safety and efficacy of the device or may otherwise not be sufficient to obtain FDA clearance or approval to market the product in the United States. Similarly, in Europe, the clinical study must be approved by a local ethics committee and in some cases, including studies with high-risk devices, by the ministry of health in the applicable country.

In August 2010, we submitted a 510(k) notification to the FDA for VergenixWD, a collagen-based non-invasive dressing. In October 2010, we received notice that the Center for Devices and Radiological Health, or CDRH, which is the FDA center with jurisdiction over medical devices, determined that the product required a submission of a PMA for regulatory approval and not a 510(k). We filed an appeal of this decision that was denied, and in April 2012, the FDA confirmed its previous determination that our product would require PMA approval prior to its marketing in the United States. We believe that most, if not all, of our products will be subject to the PMA process or will be considered combination products subject to at least some medical device regulations.

We expect, based on our prior limited interaction with the FDA in connection with our predecessor wound healing product, that our current products and pipeline products, including dermal fillers and breast implants, will be regulated as medical devices through a PMA process; however, no assurance can be given that the FDA will not impose additional, more stringent, regulatory requirements with respect to one or more of our current or future product candidates. Conducting clinical trials for our pipeline product candidates that are required to undergo the PMA process may take one to three years, depending on the composition of the product candidate under development and its designation.

We are not presently conducting any discussions with the FDA with respect to any of our products.

Post-Approval Regulation of Biologics, Drugs and Medical Devices

After a product is placed on the market, numerous regulatory requirements continue to apply. In addition to the requirements below, adverse event reporting regulations require that we report to the FDA any incident in which our product may have caused or contributed to a death or serious injury or in which our product malfunctioned and, if the malfunction were to recur, would likely cause or contribute to death or serious injury. Additional regulatory requirements include:

- product listing and establishment registration, which helps facilitate FDA inspections and other regulatory action;
- cGMP or QSR, which requires manufacturers, including third-party manufacturers, to follow stringent design, validation, testing, control, documentation and other quality assurance procedures during all aspects of the design and manufacturing process;
- labeling regulations and FDA prohibitions against the promotion of products for uncleared, unapproved or off-label use or indication;
- clearance of product modifications that could significantly affect safety or effectiveness or that would constitute a major change in intended use of one of our approved medical products;
- notice or approval of product or manufacturing process modifications or deviations that affect the safety or effectiveness of one of our approved medical products;
- post-approval restrictions or conditions, including post-approval study commitments;

- post-market surveillance regulations, which apply, when necessary, to protect the public health or to provide additional safety and effectiveness data for the medical product;

- the FDA's recall authority, whereby it can ask or, under certain conditions, order device manufacturers to recall from the market a product that is in violation of governing laws and regulations;

- regulations pertaining to voluntary recalls; and

- notices of corrections or removals.

Also, quality control and manufacturing procedures must continue to conform to current Good Manufacturing Practices, or cGMP after approval, which includes, among other things, maintenance of a stability program. The FDA periodically inspects manufacturing facilities to assess compliance with cGMP, which imposes extensive procedural, substantive, and record keeping requirements. In addition, changes to the manufacturing process are strictly regulated and, depending on the significance of the change, may require prior FDA approval before being implemented. FDA regulations also require investigation and correction of product out of specification results and impose reporting and documentation requirements upon us and any third-party manufacturers that we may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMP and other aspects of regulatory compliance. The holder of an NDA is responsible for legal and regulatory compliance for advertising and promotion of the drug product. We are required to provide to the FDA copies of all drug promotion at the time of first use and to ensure that all information disseminated conforms to the product's approved labeling and other FDA regulations and policies.

A biologic product may also be subject to official lot release, meaning that the manufacturer is required to perform certain tests on each lot of the product before it is released for distribution. If the product is subject to official lot release, the manufacturer must submit samples of each lot, together with a release protocol showing a summary of the history of manufacture of the lot and the results of all of the manufacturer's tests performed on the lot, to the FDA. The FDA may, in addition, perform certain confirmatory tests on lots of some products before releasing the lots for distribution. Finally, the FDA will conduct laboratory research related to the safety, purity, potency and effectiveness of pharmaceutical products.

Advertising and promotion of medical devices, in addition to being regulated by the FDA, are also regulated by the U.S. Federal Trade Commission, or FTC, and by state regulatory and enforcement authorities. Promotional activities for FDA-regulated products of other companies have been the subject of enforcement action brought under healthcare reimbursement laws and consumer protection statutes. Furthermore, under the federal U.S. Lanham Act and similar state laws, competitors and others can initiate litigation relating to advertising claims. In addition, we are required to meet regulatory requirements in countries outside the United States, which can change rapidly with relatively short notice. If the FDA determines that our promotional materials or training constitutes promotion of an unapproved or uncleared use, it could request that we modify our training or promotional materials or subject us to regulatory or enforcement actions. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider our promotional or training materials to constitute promotion of an unapproved use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement.

Failure by us or by our third-party manufacturers and suppliers to comply with applicable regulatory requirements can result in enforcement action by the FDA or other regulatory authorities, which may result in sanctions including, but not limited to:

- untitled letters, warning letters, fines, injunctions, consent decrees and civil penalties;

- customer notifications or repair, replacement, refunds, recall, detention or seizure of our products;

- operating restrictions or partial suspension or total shutdown of production;

- refusing or delaying requests for 510(k) clearance or PMA approvals of new products or modified products;
- withdrawing 510(k) clearances or PMA approvals that have already been granted;
- refusing to grant export approval for our products; or
- criminal prosecution.

Proteins Intended for Therapeutic Use

In the United States, proteins intended for therapeutic use, whether derived from plants, animals, microorganisms, or recombinant versions of these products, are regulated as biological products that have been transferred from the FDA Center for Biologics Evaluation and Research, or CBER, to the Center for Drug Evaluation and Research, or CDER. CDER has regulatory responsibility, including premarket review and continuing oversight over the transferred products. Cellular products, including products composed of human, bacterial, or animal cells, or from physical parts of those cells, remain under the jurisdiction of CDER.

Our products are based on our recombinant type I human collagen, or rhCollagen, a form of human collagen produced with our proprietary plant based genetic engineering technology. Therefore, we believe our underlying platform technology would be regulated as a biologic by CDER in the U.S.

Regenerative Medicine Advanced Therapy Designation

Under section 3033 of the 21st Cures Act, or Cures Act, a drug is eligible for regenerative medicine advanced therapy (RMAT) designation if (1) the drug is a regenerative medicine therapy, which is defined as a cell therapy, therapeutic tissue engineering product, human cell and tissue product, or any Combination Product using such therapies or products, except for those regulated solely under section 361 of the PHS Act and 21 C.F.R. Part 1271, (2) the drug is intended to treat, modify, reverse, or cure a serious or life-threatening disease or condition, and (3) preliminary clinical evidence indicates that the drug has the potential to address unmet medical needs for such disease or condition. If we pursue U.S. marketing approval for any of our products, we may be able to avail ourselves of this pathway or another expedited pathway.

Human Cells, Tissues, and Cellular and Tissue-Based Products Regulation

Under Section 361 of the PHS Act, the FDA issued specific regulations governing the use of human cells, tissues, and cellular and tissue-based products, or HCT/Ps, in humans. Pursuant to Part 1271 of Title 21 of the Code of Federal Regulations, or Part 1271, the FDA established a unified registration and listing system for establishments that manufacture and process HCT/Ps. The regulations also include provisions pertaining to donor eligibility determinations; current good tissue practices covering all stages of production, including harvesting, processing, manufacture, storage, labeling, packaging, and distribution; and other procedures to prevent the introduction, transmission, and spread of communicable diseases.

The HCT/P regulations strictly constrain the types of products that may be regulated solely under these regulations. Factors considered include the degree of manipulation, whether the product is intended for a homologous function, whether the product has been combined with noncellular or non-tissue components, and the product's effect or dependence on the body's metabolic function. In those instances where cells, tissues, and cellular and tissue-based products have been only minimally manipulated, are intended strictly for homologous use, have not been combined with noncellular or nontissue substances, and do not depend on or have any effect on the body's metabolism, the manufacturer is only required to register with the FDA, submit a list of manufactured products, and adopt and implement procedures for the control of communicable diseases. If one or more of the above factors has been exceeded, the product would be regulated as a drug, biological product, or medical device rather than an HCT/P.

We do not believe that Part 1271 requirements currently apply to us because we are not currently investigating, marketing or selling cellular therapy products in the U.S. If we were to change our business operations in the future, the FDA requirements that apply to us may also change, and we would potentially need to expend significant resources to comply with these requirements.

European Union

Legal Requirements for Medical Devices in the EU

EU law on medical devices is governed by Regulation EU 2017/745, or the EU MDR, which repealed and replaced Council Directive 93/42/EEC, or MDD, and Regulation 2017/746 on in vitro diagnostic medical devices. The EU MDR became fully applicable on May 26, 2021. On March 20, 2023, the EU MDR has been amended by Regulation (EU) 2023/607. Regulation (EU) 2023/607 extends the validity of certificates issued under the Medical Devices Directives (MDD) that were valid on the day of the MDR's date of application (26 May 2021) and have not been withdrawn by a Notified Body. Under certain conditions, devices certified under MDD or AIMDD may be placed on the market until 31 December 2027 for Class III and IIb implantable devices or 31 December 2028 for lower risk devices (Is, Im, IIa, IIb devices non implantable)

Under the Medical Device Regulation or EU MDR, medical devices must meet the EU MDR, requirements and have a CE mark prior to marketing in the European Union, or EU. CE marking is the uniform labeling system of products designed to facilitate the supervision and control of the EU concerning manufacturers' compliance with the various regulations and directives of the EU and to clarify the obligations imposed in the various legislative provisions in the EU. Use of a uniform product labeling indicates compliance with all of the directives and regulations required for the application of such labeling, and it is effective as a manufacturer's declaration that the product meets the required criteria and technical specifications of the relevant authorities such as health, safety, and environmental protection. CE marking ensures free trade between the EU and European Economic Area (or EEA) countries (Iceland, Liechtenstein, and Norway) and other countries that have mutual recognition agreements with regard to medical devices with the EU, in particular Turkey, and permits the enforcement and customs authorities in European countries not to allow the marketing of similar products that do not bear the CE mark. With regard to Switzerland, the respective mutual recognition agreement was not renewed in time to implement the MDR and as a result, Switzerland currently has the status of a third country with regard to EU medical devices law. As a result, EU law compliant medical devices are not freely traded with Switzerland but instead, additional requirements have to be met for CE-marked medical devices to be shipped to Switzerland, and *vice versa*.

CE-marking requires the performance of a conformity assessment procedure to establish that a product meets the essential requirements under the EU MDR. The nature of the conformity assessment procedure and the data required under it – including the question of whether or not a clinical investigation of a device is required – depends on, inter alia, the risk class of the respective device and the extent to which safety data is already available. Devices of the lowest risk class, class I, are mostly subject to mere self-certification by the manufacturer, while devices of higher risk classes, i.e., classes IIa, IIb and III, require a comprehensive quality system program, and other aspects to be reviewed by a Notified Body, or NB. An NB is a private entity vested with certain competencies and designated by the national governments of the EU member states to make independent judgments about whether a product complies with the EU requirements for medical devices and to grant the CE certificate if the manufacturer, and the product, comply with specified terms. After receiving the CE-certificate, we must pass a review carried out by the competent NB annually, under which it audits our facilities to verify our compliance with the ISO 13485 quality system standard. The CE-certificate is a requirement for the declaration of conformity we issue for our medical devices and for our legitimate affixing of the CE-mark to our products.

Certified compliance with the ISO 13485 standard, for medical device quality management systems, is beneficial for regulatory purposes in the EU with regard to devices of risk class IIa or higher. ISO standards are not mandatory, but are recognized international quality standards that are designed to ensure that we develop and manufacture quality medical devices. Other countries are also instituting regulations regarding medical devices. Compliance with these regulations requires extensive documentation and clinical reports for all of our products, revisions to labeling, and other requirements such as facility inspections to comply with the registration requirements.

In 2016, we received the CE certification for VergenixFG and VergenixSTR from our notified body DEKRA. These CE certifications were renewed in 2018 under the requirements of the MDD for 5 years i.e. until July 2023. Following the adoption of Regulation (EU) 2023/607 in March 2023, CollPlant fulfilled the applicable conditions to quality for the CE certifications extension and as a result, DEKRA (CollPlant EU NB) extended the VergenixFG CE certification to December 31, 2028 and the VergenixSTR CE certification to December 31, 2027.

Before the current CE-certificates expire, we are required to obtain new CE-certificates under the MDR Certification under the MDR is harder to achieve, as many products are subject to increased requirements due to higher risk-classification and the fact that the MDR generally provides higher requirements. Also, our general obligations *inter alia* with regard to registration, labelling, traceability, post-market surveillance have increased now that the MDR is fully applicable.

In February 2019, we received ISO 13485 certification by DEKRA for the manufacturing and purification of our rhCollagen in our production site at Rehovot. In July 2023, the scope of the ISO 13485 has been extended to also cover medical aesthetics products. The current ISO 13485 certification is valid until July 1, 2026.

Legal Requirements for Drugs in the EU

We do not believe that our products are currently subject to EU or Member States' regulation on drugs. However, given that our products are highly innovative, a risk remains that regulatory authorities, notified bodies, competitors and/or courts might be of a different opinion. Consequently, there is a risk that discussions might be started with regard to the regulatory status of our products.

If one or more of our current or future products would have the status of a drug under the law of the EU or one or more of its Member States, regulatory requirements for such product(s) would be significantly higher. In particular, a drug can only be placed on the market if it has been authorized by the competent regulatory authority either under the EU centralized procedure, the decentralized or mutual recognition procedure or under a Member State's national procedure. Marketing authorizations for drugs under all of the different authorization procedures are expensive and time consuming and require the performance of extensive pre-clinical and clinical research. If one or more of our products would be considered drugs by a regulatory authority, notified body or court of the EU or a Member State, it is possible that we would be forced to take the respective product(s) off the market until they have received marketing approval under pharmaceutical law. In addition, this might also lead to administrative fines, criminal prosecution and/or claims raised by customers and/or competitors.

Other U.S. Federal Healthcare Laws and Regulations

Healthcare providers, physicians, and third-party payors play a primary role in the recommendation and medical devices that are granted marketing approval. In the United States, we are subject to laws and regulations pertaining to healthcare fraud and abuse, including anti-kickback laws and physician self-referral laws that regulate the means by which companies in the healthcare industry may market their products to hospitals and healthcare providers and may compete by discounting the prices of their products. The delivery of our products is subject to regulation regarding reimbursement, and federal healthcare laws apply when a customer submits a claim for a product that is reimbursed under a federally funded healthcare program. These rules require that we exercise care in structuring our sales and marketing practices and customer discount arrangements.

Arrangements with healthcare providers, third-party payors, and other customers are subject to broadly applicable fraud and abuse and other healthcare laws and regulations, including the following:

- the federal healthcare Anti-Kickback Law prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving, or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order, or recommendation of, any good or service for which payment may be made, in whole or in part, under a federal healthcare program such as Medicare and Medicaid;

- the U.S. False Claims Act imposes civil penalties, and provides for civil whistleblower or *qui tam* actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease, or conceal an obligation to pay money to the federal government;

- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act and its implementing regulations, also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security, and transmission of individually identifiable health information;

- the federal false statements statute prohibits knowingly and willfully falsifying, concealing, or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items, or services;

- the federal transparency requirements under the Affordable Care Act require manufacturers of drugs, devices, and medical supplies to report to the U.S. Department of Health and Human Services information related to payments, ownership and investment interest and other transfers of value to physicians, dentists, physician assistants and other health care professionals and teaching hospitals; and

- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers.

Healthcare providers that purchase medical devices generally rely on third-party payors, including, in the United States, the Medicare and Medicaid programs and private payors, such as indemnity insurers, employer group health insurance programs, and managed care plans, to reimburse all or part of the cost of the products. As a result, demand for our products is and will continue to be dependent in part on the coverage and reimbursement policies of these payors. The manner in which reimbursement is sought and obtained varies based upon the type of payor involved and the setting in which the product is furnished and utilized. Reimbursement from Medicare, Medicaid, and other third-party payors may be subject to periodic adjustments as a result of legislative, regulatory, and policy changes as well as budgetary pressures. Possible reductions in, or eliminations of, coverage or reimbursement by third-party payors, or denial of, or provision of uneconomical reimbursement for new products, may affect our customers' revenue and ability to purchase our products. Any changes in the healthcare regulatory, payment, or enforcement landscape relative to our customers' healthcare services has the potential to significantly affect our operations and revenue.

Other Approvals

Our international operations, as well as being an Israeli company, subject us to laws regarding sanctioned countries, entities, and persons; customs, import-export, and laws regarding transactions in foreign countries; and the U.S. Foreign Corrupt Practices Act and local anti-bribery and other laws regarding interactions with healthcare providers. Among other things, these laws restrict, and in some cases can prevent, companies from directly or indirectly selling goods, technology, or services to people or entities in certain countries. In addition, these laws require that we exercise care in structuring our sales and marketing practices in foreign countries.

In addition to the above regulations, we are and may be subject to regulation under country-specific federal and state laws, including, but not limited to, requirements regarding record keeping and the maintenance of personal information, including personal health information. As a public company whose securities are registered pursuant to the Securities Act, we are subject to U.S. securities laws and regulations, including the Sarbanes-Oxley Act. We also are subject to other present, and could be subject to possible future, local, state, federal, and non-U.S. regulations in countries in which we will distribute our products.

The Innovation Law and the IIA

A recipient of an IIA grant, or, Recipient Company, is subject to various obligations and restrictions under the Innovation Law and the IIA's rules and guidelines, with respect to the use of its IIA Funded Know-How, including the following:

- **Royalty Payment Obligation**. In general, the Recipient Company is obligated to pay the IIA royalties from any income deriving from products (and related know-how and services), whether received by the Recipient Company or any affiliated entity, developed (in whole or in part), directly or indirectly, as a result of an Approved Program, or deriving therefrom, at rates which are determined under the IIA's rules and guidelines (currently a yearly rate of between 3% to 5% on sales of products or services developed under the Approved Programs, depending on the type of the Recipient Company - i.e., whether it is a "Small Company," or a "Large Company" as such terms are defined in the IIA's rules and guidelines), up to the aggregate amount of the total grants received by the IIA, plus Annual Interest For a File (as such term is defined in the IIA's rules and guidelines). As of December 31, 2024, we paid royalties to the IIA in total amount of $3.1 million.

- **Reporting Obligations**. The Recipient Company is subject to certain reporting obligations (such as, periodic reports regarding the progress of the research and development activities under the Approved Programs and the related research expenses, and regarding the scope of sales of the Recipient Company's products). In addition, any direct change in control of a Recipient Company must be notified to the IIA. In the event that a non-Israeli entity or a non-Israeli citizen or resident person becomes an "Interested Party" (as such term is defined in the Israeli Securities Law, 5728-1968, or, the Israeli Securities Law) in the Recipient Company, notification to the IIA is required, accompanied by a written undertaking (in the form available on the IIA's website) by such party to be bound by the Innovation Law, the regulations promulgated thereunder, the IIA's rules and guidelines and the terms of the Approved Program.

- **Local Manufacturing Obligation**. Products developed using the IIA grants must, as a general matter, be manufactured in Israel. The transfer of manufacturing capacity outside of Israel in a manner that exceeds the manufacturing capacity that was declared in the Recipient Company's original IIA grant application, is subject to prior written approval from the IIA (except for the transfer of less than 10% of the manufacturing capacity in the aggregate, which event requires only a notice to the IIA, which shall be provided in writing prior to the transfer of such manufacturing rights abroad, while the IIA has a right to deny such transfer within 30 days following the receipt of such notice). In general, the transfer of manufacturing capacity outside of Israel may be subject to an increase in the royalties' cap (depending, *inter alia,* on the manufacturing volume that is performed outside of Israel) and such transfer will be subject to payment of royalties in accelerated rate.

- **IIA Funded Know-How transfer limitation**. Under the IIA's rules and guidelines, a Recipient Company is prohibited from transferring the IIA Funded Know-How outside of Israel except with the approval of the IIA Research Committee and in certain circumstances, subject to certain payments to the IIA calculated according to formulas provided under the IIA's rules and guidelines (which are capped to amounts specified under such rules and guidelines, generally up to 6 time the grants received plus Annual Interest, as such term is defined in the IIA's rules and guidelines), or the Redemption Fee. For calculating the Redemption Fee which shall be paid to the IIA in the event of a transfer of IIA Funded Know-How outside of Israel, *inter alia*, the following factors will be taken into account: the scope of the IIA support received, the royalties that have already paid to the IIA, the amount of time that has lapsed since the Recipient Company has finalized the IIA Approved Program, the sale price and the form of transaction. A transfer for the purpose of the Innovation Law means an actual sale of the IIA Funded Know-How, or any other transaction which in essence constitutes a transfer of such know-how (such as, providing an exclusive license to a foreign entity for R&D purposes, which precludes the Recipient Company from further using such IIA Funded Know-How). A mere license solely to market products resulting from the IIA Funded Know-How would not be deemed a transfer for the purpose of the Innovation Law.

  Subject to the IIA's prior approval, a Recipient Company may transfer IIA Funded Know-How to another Israeli company, provided that the acquiring company assumes all of the Recipient Company's responsibilities towards the IIA. Such transfer will not be subject to the payment of the Redemption Fee, however, the income from such transaction will generally be subject to the obligation to pay royalties to the IIA (other than in specific circumstances that will be examined by the IIA, mainly when the transfer is between related entities).

- **IIA Funded Know-How license limitation**. The grant to a foreign entity of a right to use the IIA Funded Know-How for R&D purposes (which does not entirely prevent the Recipient Company from using the IIA Funded Know-How) is subject to receipt of the IIA's prior approval. This approval is subject to payment to the IIA in accordance with the formulas stipulated in the IIA rules (such payment shall be no less than the amount of the IIA grants received (plus Annual Interest), and no more than the cap stated in the IIA rules and will generally be due only upon the receipt of the license fee from the licensee).

The obligation to comply with the Innovation Law and the IIA's rules and guidelines (including with respect to the restriction of the transfer of IIA Funded Know-How and manufacturing rights outside of Israel) remains in effect even after full repayment of all amounts payable to the IIA. Once a Redemption Fee is paid on a transfer of IIA Funded Know-How outside Israel, all obligations towards the IIA (including the royalty obligation) cease.

Israeli Ministry of Agriculture

The process of growth of transgenic plants and the treatment thereof is subject to the regulations published by the Israeli Ministry of Agriculture and the approval of the Ministry of Agriculture to engage in the cultivation of recombinant plants. Although the Ministry of Agriculture requirements do not necessarily apply to our operations, we hold a valid permit from the Plant Protection and Inspection Services Administration, for growing tobacco plants in greenhouses in our site at Yessod Hama'ala, Israel, as well as in all of our subcontractors' facilities.

Business Licensing

Under the Israeli Licensing of Businesses Law, to which our production sites and laboratories are subject, operating a business without a license or temporary permit is a criminal offense. Both of our sites in Rehovot, and our production site at Yessod Hama'ala, have valid business licenses.

Planning and Zoning

The Israeli Planning and Zoning Law, sets provisions and obligations, *inter alia*, regarding the licensing process for a new building, including building permits, non-conforming use and easements, the supervision over its construction, and the required occupancy permits. According to the Planning and Zoning Law, work or use of land without a permit where such permit is required, a deviation from the permit granted, or use of agricultural land in violation of the law, constitutes a criminal offense.

We have recently learned upon internal inspection that permits for certain of the structures on our production site at Yessod Hama'ala are missing. We are in correspondence with the relevant authorities, including the regional council, and are in the process of obtaining the necessary permits. To date, the site remains open and operational, and we have not experienced any adverse effects resulting from our need to obtain the said permits.

Employees

As of March 15, 2025, we had 57 employees, including 17 in research and development, 27 in manufacturing and 13 in sales, general and administrative positions. 10 of our employees have either MDs or PhDs. All of our employees are located in Israel. We believe our employee relations are good.

In addition, we engage consultants and service providers through contractual agreements for specific company projects.

Israeli labor laws govern the length of the workday, minimum wages for employees, procedures for hiring and dismissing employees, determination of the scope of severance pay, annual leave, sick days, advance notice of termination of employment, equal opportunity and anti-discrimination laws, and other conditions of employment. Subject to specified exceptions, Israeli law generally requires severance pay upon the retirement, death, or dismissal of an employee. We fund our ongoing severance obligations by making monthly payments to insurance policies that comply with the applicable Israeli legal requirements. All of our current employees have agreed that upon termination of their employment, they will be entitled to receive only the amounts accrued in the insurance policies with respect to severance pay. Furthermore, Israeli employers and employees are required to make payments to the National Insurance Institute, which is similar to the U.S. Social Security Administration.

None of our employees currently work under any collective bargaining agreements.

Environmental, Health, and Safety Matters

Our research, development, and manufacturing processes involve the controlled use of certain hazardous materials. Therefore, we are subject to extensive environmental, health, and safety laws and regulations in a number of jurisdictions in Israel, governing, among other things: the use, storage, registration, handling, emission, and disposal of chemicals, waste materials, and sewage; chemicals, air, water, and ground contamination; air emissions; and the cleanup of contaminated sites, including any contamination that results from spills due to our failure to properly dispose of chemicals, waste materials, and sewage. Our operations at our Rehovot manufacturing facility use chemicals and produce waste materials and sewage. Our activities require permits from various governmental authorities including local municipal authorities, the Ministry of Environmental Protection, and the Ministry of Health. The Ministry of Environmental Protection, the Ministry of Health, local authorities, and the municipal water and sewage company conduct periodic inspections in order to review and ensure our compliance with various regulations.

These laws, regulations, and permits could potentially require the expenditure by us of significant amounts for compliance or remediation. We believe that our environmental, health, and safety procedures for handling and disposing of these materials comply with the standards prescribed by the controlling laws and regulations. If we fail to comply with such laws, regulations, or permits, we may be subject to fines and other civil, administrative, or criminal sanctions, including the revocation of permits and licenses necessary to continue our business activities. In addition, we may be required to pay damages or civil judgments with respect to third-party claims, including those relating to personal injury (including exposure to hazardous substances we use, store, handle, transport, manufacture, or dispose of), property damage, or contribution claims. These risks are managed to minimize or eliminate associated business impacts. Some environmental, health, and safety laws allow for strict joint and several liability for remediation costs, regardless of comparative fault. We may be identified as a responsible party under such laws. Such developments could have a material adverse effect on our business, financial condition, and results of operations as these kinds of liabilities could exceed our resources. We could be subject to a regulatory shutdown of a facility that could prevent the distribution and sale of products manufactured in such facility for a significant period of time, and we could suffer a casualty loss that could require a shutdown of the facility in order to repair it, any of which could have a material, adverse effect on our business. Although we continuously strive to maintain full compliance with respect to all applicable global environmental, health, and safety laws and regulations, we could incur substantial costs to fully comply with future laws and regulations, and our operations, business, or assets may be negatively affected.

In addition, compliance with laws and regulations relating to environmental, health, and safety matters is an ongoing process and is often subject to change. In the event of any changes or new laws or regulations, we could be subject to new compliance measures or to penalties for activities which were previously permitted. For instance, Israeli regulations were promulgated in 2012 relating to the discharge of industrial sewage into the sewer system. These regulations establish new and potentially significant fines for discharging forbidden or irregular sewage into the sewage system. We have compliance procedures in place for employee health and safety programs, driven by a centrally led organizational structure that ensures proper implementation, which is essential to our overall business objectives. We invest resources in creating a green production environment and in the treatment and disposal of waste using environmentally friendly processes. We consult with environmental consultants for direction on environmental issues.

In September 2023, we announced that we joined the United National Global Compact, the world’s largest initiative for sustainable and responsible corporate governance. As a member of this voluntary leadership platform, we strengthen our commitment to operate sustainably as it is also producing sustainable alternatives to the regenerative and aesthetics medicine products and technologies that currently exist.

On July 29, 2024, we released our inaugural Environmental, Social and Corporate Governance (ESG) and Sustainability Report covering the fiscal year 2023. The report reflects our wide commitment to fostering environmental sustainability and enhancing human health, as well as advancing social and corporate governance objectives that contribute to the Company’s impact.

Legal Proceedings

From time to time, we may become involved in legal proceedings or be subject to claims arising in the ordinary course of our business. We are currently not a party to any material legal or administrative proceedings and, are not aware of any pending or threatened material legal or administrative proceedings against us.

C. Organizational Structure

We currently have two subsidiaries: our wholly owned subsidiary CollPlant Ltd., which is incorporated in the State of Israel, and CollPlant Inc., a wholly owned subsidiary of CollPlant Ltd., which is incorporated in Delaware.

D. Property, Plant and Equipment

Our corporate headquarters and research lab center are located in the Weizmann Science Park in Rehovot, Israel. We entered into a lease agreement in November 2018, for an aggregate of approximately 13,450 square feet of office and laboratory space, which was amended in September 2021, to include additional approximately 2,800 square feet. In April 2024, the term of the lease agreement was automatically extended for an additional five years, until April 2029. In April 2024, we further amended the lease agreement to include an additional approximately 4,682 square feet.

The monthly rent under the aforementioned lease agreement is approximately $0.057 million. To date, we have invested approximately $1.6 million in establishment of the infrastructure, offices, labs and equipment in our space, net of participation by the landlord.

The research facilities serve us for development of our product pipeline, including bioinks for 3D bioprinting of tissues and organs, dermal fillers and breast implants for medical aesthetics. The majority of our research and development work is carried out at our research laboratories in Weizmann Science Park in Rehovot, Israel.

The agricultural research process of our rhCollagen is carried out at our site in Yessod Hama'ala, Israel. We produce our rhCollagen and bioink in our two production sites, in Yessod Hama'ala and in Rehovot.

We lease areas in Yessod Hama'ala, Israel, of approximately 64,583 square feet pursuant to a lease agreement expiring on April 30, 2027.

In addition, in July 2016, we leased additional space in Rehovot, Israel, of approximately 6,329 square feet for purification and production activities pursuant to a lease agreement expiring on December 31, 2026, with an option to extend the lease for an additional four years.

In late 2021, we initiated a plan to upgrade our production site in Israel into a large-scale integrated facility, in order to accommodate expected future demand increase. We will continue with the plan once there is a surge in demand and the necessary funds are secured for its execution.

We believe that our existing facilities are adequate for our near-term needs. When our leases expire, we may look for extension periods or alternate space for our operations. We believe that suitable additional or alternative space and area would be available if required in the future on commercially reasonable terms.

ITEM 4A. UNRESOLVED STAFF COMMENTS

Not applicable.

ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS

You should read the following discussion and analysis of our financial condition and results of operations together with the section titled "Item 3.A.—Selected Financial Data" and our consolidated financial statements and related notes included elsewhere in this Annual Report on Form 20-F. This discussion and other parts of this Annual Report on Form 20-F contain forward-looking statements that involve risk and uncertainties, such as statements of our plans, objectives, expectations, and intentions. Our actual results could differ materially from those discussed in these forward looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in the section titled "Item 3.D.—Risk Factors" and elsewhere in this Annual Report in Form 20-F.

Overview

We are a regenerative and aesthetic medicine company focused on medical aesthetics and 3D bioprinting of tissues and organs. Our products are based on our recombinant human collagen (rhCollagen) that is produced with our proprietary plant based genetic engineering technology. These products address indications for the diverse fields of tissue repair, aesthetics and organ manufacturing, and are ushering in a new era in regenerative and aesthetic medicine. Our collaborations include, among others, AbbVie, STEMCELL, the Advanced Regenerative Manufacturing Institute, Stratasys and the RegenMed Development Organization.

We are in collaboration with AbbVie under the AbbVie Development Agreement, pursuant to which we and AbbVie are in the development and commercialization of dermal and soft tissue filler products for the medical aesthetics market, using our rhCollagen technology and AbbVie's technology.

Our rhCollagen bioink product line is ideal for 3D bioprinting of tissues and organs. We are developing 3D bioprinted breast implants for regeneration of breast tissue, aim to provide a revolutionary alternative to the current practices. The implants in development are printed and loaded with compositions that are based on rhCollagen and other components. These implants are intended to promote tissue regeneration and degrade in synchronization with the development of a natural breast tissue.

In recent years, we have financed our operations primarily with revenues from sales of our products, license of our technology and development milestone achievement payments from business partner, as well as from net proceeds from private and public offerings on Nasdaq Global Market. Prior to this, we financed our operations primarily from public offerings of our securities on the TASE, participation of business partners in product development collaborations, and government grants from the IIA.

Financial Operations Overview

Revenue

Our ability to generate significant revenues will depend on the successful commercialization of our rhCollagen-based bioinks and products, our strategic partners successful commercialization of the dermal filler product that is in a clinical phase, and on our ability to establish and maintain business collaborations with leading companies for 3D bioprinting of organs and tissues, and for medical aesthetics. In the year ended December 31, 2024, we generated revenues of approximately $0.5 million, mainly from the sales of our bioink and rhCollagen products.

Our revenues are recorded in the amount of consideration to which we expect to be entitled in exchange for performance obligations upon transfer of control to the customer.

Cost of Revenues

Cost of revenues in our proprietary products and services includes expenses for the manufacturing of products such as raw materials, payroll, utilities, laboratory costs, share-based compensation and depreciation. Cost of revenue also includes royalties to the IIA and provisions for the costs associated with manufacturing scraps and inventory write offs.

Our balance sheet liabilities include current obligations regarding royalties that we are obligated to pay to the IIA based on sales of our products for the second half of the year, which were paid in February 2025. Our cost of revenues include royalties expenses regarding royalties on our sales to the IIA. For more information, see "Item 3.D. Risk Factors—Risks Related to Our Financial Condition and Capital Requirements—The IIA grants we have received in the past for research and development expenditures may restrict our ability to manufacture products and transfer know-how outside of Israel and require us to satisfy specified conditions", and Note 6 in our consolidated financial statements for the year ended December 31, 2024.

Operating Expenses

Research and Development Expenses

Research and development expenses consist of costs incurred for the development of our rhCollagen-based products. Those expenses include:

- employee-related expenses, including salaries and share-based compensation expenses for employees in research and development functions;
- expenses incurred in operating our laboratories;
- expenses incurred under agreements with CROs and investigative sites that conduct our pre-clinical trials;
- expenses relating to outsourced and contracted services, such as external laboratories, consulting, and advisory services;
- supply, development, and manufacturing costs relating to clinical trial materials;
- maintenance of facilities, depreciation, and other expenses, which include direct and allocated expenses for rent and insurance, net of expenses capitalized to inventory; and
- costs associated with preclinical and clinical activities.

Research and development activities are the primary focus of our business. Products in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. We expect that our research and development expenses will continue to be significant in absolute dollars in future periods as we continue to invest in research and development activities related to the development of our products.

Our total research and development expenses for the years ended December 31, 2024, December 31, 2023, and December 31, 2022 were $10.5 million, $10.5 million, and $10.3 million, respectively. We did not apply for grants from the IIA since 2019 and we have charged all research and development expenses to operations as they are incurred.

There are numerous factors associated with the successful commercialization of any of our products, including future trial design and various regulatory requirements, many of which cannot be determined with accuracy at this time. Additionally, future commercial and regulatory factors beyond our control will affect our clinical development programs and plans.

General, Administrative, and Marketing Expenses

Our general and administrative expenses consist principally of:

- employee-related expenses, including salaries, benefits, and related expenses, including share-based compensation expenses;
- legal and professional fees for auditors, investor relations, and other consulting expenses not related to research and development activities;
- cost of offices, communication, and office expenses;
- information technology expenses;

- business development and marketing activities;
- Stock exchange fees and related services; and
- Board members related expenses, including fees and directors' liability insurance premiums.

Financial Income/Financial Expenses

Financial income includes interest income regarding short-term deposits and restricted deposits. Financial expenses consist of bank and other fees and exchange rate differences from the strengthening of the U.S. dollars compared to NIS.

Taxes on Income

We do not generate taxable income in Israel, as we have historically incurred operating losses resulting in carry forward tax losses. As of December 31, 2024, we have incurred operating losses of approximately $35.2 million for CollPlant Biotechnologies Ltd. and $46.0 million for CollPlant Ltd. We anticipate that we will be able to carry forward these tax losses indefinitely to future tax years assuming that we utilize them at the first opportunity. Accordingly, we do not expect to pay taxes in Israel until we have taxable income after the full utilization of our carry forward tax losses.

The standard corporate tax rate in Israel is 23%. Under the Investment Law, and other Israeli laws, we may be entitled to certain additional tax benefits, including reduced tax rates, accelerated depreciation, and amortization rates for tax purposes on certain assets and amortization of other intangible property rights for tax purposes.

A. Operating Results

The table below provides our results of operations for the years ended December 31, 2024, 2023, and 2022.

	Year ended December 31,		
	2024	**2023**	**2022**
	(USD in thousands)		
Statement of operations data:			
Revenues	$ 515	$ 10,959	$ 299
Cost of revenues	1,625	1,991	400
Gross profit (loss)	(1,110)	8,968	(101)
Research and development expenses	10,515	10,484	10,255
General, administrative, and marketing expenses	5,626	5,996	6,741
Total operating loss	17,251)	(7,512)	(17,097)
Financial income, net	642	493	172
Net loss	$ 16,609)	$ (7,019)	$ (16,925)

Revenues

We generated revenues from the sale of our bioink, rhCollagen, and VergenixFG in the amount of $0.5 million in the year ended December 31, 2024 compared to $11.0 million in the year ended December 31, 2023. The decrease in revenues is mainly related to (i) the achievement of a milestone with respect to the AbbVie Development Agreement, which triggered a $10 million payment from AbbVie to us in 2023, and (ii) $0.4 million in sales of rhCollagen products and VergenixFG.

In the year ended December 31, 2023 we generated revenues from the achievement of a milestone under the AbbVie Development Agreement, and from the sale of our bioInk, rhCollagen, and VergenixFG products, in the total amount of $11.0 million compared to $0.3 million in year ended December 31, 2022. The increase in revenues is mainly related to the achievement of a milestone with respect to the AbbVie Development Agreement, which triggered a $10 million payment and a $0.7 million increase in sales of rhCollagen products.

Cost of revenues

We incurred cost of revenue in the amount of $1.6 million in the year ended December 31, 2024, compared to $2.0 million in the year ended December 31, 2023. The decrease in cost of revenues in the amount of approximately $0.4 million is mainly comprised: (i) approximately $0.3 million in royalty expenses to the IIA, mainly relating to the milestone achievement under the AbbVie Development Agreement, and (ii) approximately $0.3 million relating to bioinks and rhCollagen sales offset by approximately $0.2 million related to inventory impairments.

We incurred cost of revenue in the amount of $2.0 million in the year ended December 31, 2023, compared to $0.4 million in the year ended December 31, 2022. The increase in cost of revenues in the amount of approximately $1.6 million is mainly comprised of: (i) approximately $0.3 million in royalty expenses to the IIA, mainly relating to the milestone achievement under the AbbVie Development Agreement, (ii) approximately $0.7 million relating to bioinks, VergenixFG, and rhCollagen sales, and (iii) approximately $0.6 million related to inventory write offs.

Research and Development Expenses

We incurred research and development expenses amounting to $10.5 million in the year ended December 31, 2023 and 2024.

We incurred research and development expenses amounting to $10.5 million in the year ended December 31, 2023, compared to $10.3 million in the year ended December 31, 2022. The increase in expenses amounting to approximately $0.2 million mainly derived from employee salary expenses, including recruitment of new employees for development of new products in 3D bioprinting and medical aesthetics and share based compensation expenses.

General, Administrative, and Marketing Expenses

We incurred general, administrative, and marketing expenses of $5.6 million in the year ended December 31, 2024, compared to $6.0 million in the year ended December 31, 2023. The decrease in expenses amounting to approximately $0.4 million is mainly comprised of: (i) a decrease of $0.3 million in share based compensation expenses mainly related to options grant in 2022 and 2020; and (ii) a decrease of $0.1 million in insurance policy costs.

We incurred general, administrative, and marketing expenses of $6.0 million in the year ended December 31, 2023, compared to $6.7 million in the year ended December 31, 2022. The decrease in expenses amounting to approximately $0.7 million is mainly comprised of: (i) a decrease of $0.2 million in employees' salaries expense, (ii) a decrease of $0.4 million in share based compensation expenses mainly related to options grant in 2022 and (iii) a decrease of $0.1 million in insurance policy costs.

Financial Income, Net

Financial income, net in the year ended December 31, 2024 totaled $0.6 million compared to $0.5 million in the year ended December 31, 2023.

Financial income, net in the year ended December 31, 2023 totaled $0.5 million compared to $0.2 million in the year ended December 31, 2022.

Financial income, net is mainly attributed to interest received from the Company's short term cash deposits.

Recent Accounting Pronouncements

Certain recently issued accounting pronouncements are discussed in Note 2, Significant Accounting Policies, to the consolidated financial statements included in "Item 18. Financial Statements" of this Annual Report.

B. Liquidity and Capital Resources

Our primary uses of cash are to fund working capital requirements, research and development expenses and capital expenditures. Historically, we have funded our operations primarily through cash flow from operations (including sales of our proprietary products and distribution products), payments received in connection with strategic partnerships (including milestone payments from collaboration agreements), issuances of ordinary shares and warrants (including public offerings on the TASE, Nasdaq Global Market and private placements) and government grants from the IIA. The balance of cash and cash equivalents as of December 31, 2024 and 2023 totaled $11.9 million and $26.7 million, respectively. In February 2021 we completed a registered direct offering that resulted in gross proceeds of $35 million and in the same month, we received a $14 million consideration for the license granted to AbbVie under the AbbVie Development Agreement. In June 2023, we announced the achievement of a milestone with respect to the dermal filler product under the AbbVie Development Agreement, which triggered a $10 million payment from AbbVie to us. In February 2025, we announced an additional achievement of a milestone with respect to dermal filler product under the AbbVie Development Agreement, which triggered a $2 million payment from AbbVie to us. Although in the past we have received payments under the AbbVie Development Agreement, there can be no assurance that we will receive any further payments under the AbbVie Development Agreement.

We plan to fund our future operations through continued sales of our proprietary products, commercialization and or out-licensing of our rhCollagen and bioink technology, and raising additional capital through the issuance of equity or debt.

Our cash requirements from known contractual obligations within the next twelve months include:

- Lease liabilities in the amount of $0.9 million. For more information see Note 5 to our consolidated financial statements for the year ended December 31, 2024; and
- Trade and other payables in the amount of $2.2 million, which include amounts related to suppliers, salaries and other liabilities with payment term of less than one year.

Our long-term cash requirements under our various contractual obligations include:

- Lease liabilities in the amount of $2.7 million. For more information, see Note 5 to our consolidated financial statements for the year ended December 31, 2024.

Cash Flows

The following table summarizes our consolidated statement of cash flows for the years ended December 31 2024 , 2023, and 2022.

	Year ended December 31,		
	2024	2023	2022
	(USD in thousands)		
Net cash provided by (used in):			
Operating activities	(14,093)	(2,763)	(13,698)
Investing activities	(539)	(1,156)	28,922
Financing activities	9	1,108	1,874

Net Cash Provided by (Used in) Operating Activities

Net cash provided by or used in operating activities resulted primarily from our net income or losses, adjusted for non-cash changes in components of working capital. Adjustments to net loss for non-cash items include mainly depreciation and amortization, share-based compensation and exchange differences on cash and cash equivalents. This cash flow mainly reflects the cash needed for funding the products and pipeline products development and our management costs during the applicable periods.

Net cash used in operating activities in the year ended December 31, 2024 totaled $14.1 million and consisted primarily of (i) net loss of $16.6 million, adjusted for non-cash items including depreciation of $1.0 million, share-based compensation of $1.7 million, and net financing expenses of $0.1 million, and (ii) a net change in operating assets and liabilities of $0.4 million which was mainly attributable to a decrease in accrued liabilities.

Net cash used in operating activities in the year ended December 31, 2023 totaled $2.8 million and consisted primarily of (i) net loss of $7.0 million, adjusted for non-cash items including depreciation of $1.1 million, share-based compensation of $1.9 million and exchange differences on cash and cash equivalents of $0.4 million, and (ii) a net change in operating assets and liabilities of $0.8 million , which was mainly attributable to a decrease in inventories of $0.7 million.

Net cash used in operating activities in the year ended December 31, 2022 totaled $13.7 million and consisted primarily of (i) net loss of $16.9 million, adjusted for non-cash items including depreciation of $1.1 million, share-based compensation of $2.2 million, gains from short-term cash deposits of $0.1 million, and (ii) a net change in operating assets and liabilities of $0.5 million.

Net Cash Provided by (Used in) Investing Activities

Net cash used in investing activities was $0.5 million during the year ended December 31, 2024 and net cash provided by investing activities was $1.2 million during the year ended December 31, 2023. The decrease is mainly attributed to the purchase of property and equipment.

Net cash used in investing activities was $1.2 million during the year ended December 31, 2023 and net cash provided by investing activities was $28.9 million during the year ended December 31, 2022. The decrease is mainly attributed to repayment and investment in short-term cash deposits during the year ended December 31, 2022.

Net Cash Provided by Financing Activities

Net cash provided by financing activities was $0.01 million for the year ended December 31, 2024 compared to $1.1 million in the year ended December 31, 2023.

Net cash provided by financing activities was $1.1 million for the year ended December 31, 2023 compared to $1.9 million in the year ended December 31, 2022.

Cash provided by financing activities is attributed to proceeds from the exercise of warrants and options into shares.

Cash and Funding Sources

The table below summarizes our sources of funding for the years ended December 31, 2024, 2023, and 2022:

	Issuance of Ordinary Shares and Warrants	Strategic Collaborations	Total
		(USD in thousands)	
Year ended December 31, 2024	9	-	9
Year ended December 31, 2023	1,108	10,000	11,108
Year ended December 31, 2022	1,874	-	1,874

Funding Requirements

Since our inception, we have incurred significant losses. Our net loss was $16.6 million and $7.0 million for the years ended December 31, 2024 and 2023, respectively. Our negative cash flows from operating activities was $14.1 million. Our cash and cash equivalent as of December 31, 2024 totaled $11.9 million. As of December 31, 2024, we had an accumulated deficit of $113.4 million. We expect to continue to incur expenses and operating losses for the foreseeable future. The net losses we incur may fluctuate significantly from quarter to quarter. Our existing cash and cash equivalents as of the date of this Annual Report on Form 20-F is approximately $11.9 million.

We recently updated our expense forecast and initiated a cost cutting and workforce reduction plan which resulted in a reduction of workforce by approximately 20% and based on current estimates, we believe this will allow us to continue our business activities including those related to its primary research and development programs until at least the second quarter of 2026.

We expect to incur future net losses and the transition to profitability is dependent upon, among other things, the successful development and commercialization of our products and product candidates including the dermal filler product being developed by AbbVie, the establishment of contracts for the distribution of new product lines, any of which, or in combination, would contribute to the achievement of a level of revenue adequate to support the cost structure. Until we achieve profitability or generate positive cash flows, we will continue to need to raise additional cash to finance our operations and to fund future operations through existing cash on hand, additional private and/or public offerings of debt or equity securities, any additional milestone payments that may be received under the AbbVie Development Agreement. Notwithstanding, there can be no assurance that we will be able to raise additional funds, receive additional milestone payments or achieve or sustain profitability or positive cash flows from operations, and even if available, whether it will be on terms acceptable to us or in amounts required.

Accordingly, our board of directors approved a contingency plan, to be implemented if needed, in whole or in part, at its discretion, to allow us to continue its operations and meet our cash obligations. The contingency plan consists of cost reduction, which include mainly the reduction in subcontractors' expenses, headcount and compensation paid to key management.

We believe that our existing capital resources will be adequate to satisfy our expected liquidity requirements for at least twelve months from the filing date. We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect.

Our present and future funding requirements will depend on many factors, including, among other things:

- the number of potential new products we identify and decide to develop;
- the progress, timing, and completion of preclinical testing and clinical trials which are based on our bioink, medical aesthetics, and any future pipeline product;
- selling and marketing activities undertaken in connection with the commercialization of our products;

- the costs of upscaling our manufacturing capabilities;
- costs involved in the development of distribution channels, and for an effective sales and marketing organization, for the commercialization of our products in Europe;
- the time and costs involved in obtaining regulatory approvals and any delays we may encounter as a result of evolving regulatory requirements or adverse results with respect to any of these products; and
- the costs involved in filing patent applications and maintaining and enforcing patents or defending against claims or infringements raised by third parties.

For more information as to the risks associated with our future funding needs, see "Item 3.D. Risk Factors—We will need to raise additional funding, which may not be available on acceptable terms, or at all. Failure to obtain additional capital when needed may force us to delay, limit, or terminate our product development efforts or other operations."

C. Research and Development, Patents and Licenses

See above, under Item 5 – "Research and Development Expenses."

D. Trend Information

We are in a development stage with regard to different medical and aesthetics products, and are in early stages of commercialization of our bioink products for customers that develop technologies for 3D-bioprinting of tissues and organs and the medical aesthetics market. It is not possible for us to predict with any degree of accuracy the outcome of our research, development, or commercialization efforts. As such, it is not possible for us to predict with any degree of accuracy any known trends, uncertainties, demands, commitments or events that are reasonably likely to have a material effect on our net sales or revenues, income from continuing operations, profitability, liquidity or capital resources, or that would cause reported financial information to not necessarily be indicative of future operating results or financial condition. However, to the extent possible, certain trends, uncertainties, demands, commitments and events are in this "Operating and Financial Review and Prospects."

E. Critical Accounting Estimates

Our critical accounting estimates include the areas where we have made what we consider to be particularly difficult, subjective or complex judgments in making estimates, and where these estimates can significantly affect our financial results under different assumptions and conditions. We prepare our financial statements in conformity with U.S GAAP. As a result, we are required to make estimates, judgments and assumptions that we believe are reasonable based upon the information available. These estimates, judgments and assumptions affect the reported amounts of assets and liabilities at the date of the financial statements and reported amounts of revenue and expenses during the periods presented. Actual results could be different from these estimates. Critical estimates and assumptions made by management include:

Estimates of share-based compensation fair value

Share-based compensation reflects the compensation expense of our share award programs granted to employees which compensation expense is measured at the grant date fair value of the award. The grant date fair value of share-based compensation is recognized as an expense over the requisite service period. We recognize compensation expense for awards conditioned only on continued service that have a graded vesting schedule using the accelerated method based on the multiple-option award approach, and classify these amounts in our statement of operations based on the department to which the related employee reports.

Award Valuation

We selected the Black-Scholes option pricing model as the most appropriate method for determining the estimated fair value of the share-based compensation.

For the purpose of the evaluation of the fair value and the manner of the recognition of share-based compensation, our management is required to estimate, among others, various subjective and complex parameters that are included in the calculation of the fair value of the award as well as our results and the number of awards that will vest. These parameters include the expected volatility of our share price over the expected term of the awards, the risk-free interest rate assumption, and expected dividends.

ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES

A. Directors and Senior Management

The following table sets forth certain information relating to our directors and senior management as of March 15, 2025. Unless otherwise stated, the address for our directors and senior management is at the Company's registered address c/o 4 Oppenheimer, Weizmann Science Park, P.O. Box 4132, Rehovot 7670104, Israel.

Name	Age	Position
Senior Management		
Yehiel Tal	72	Chief Executive Officer and Director
Eran Rotem, CPA	57	Deputy CEO and Chief Financial Officer
Oren Fahimipoor	43	Vice President, Operations
Dr. Philippe Bensimon	59	Vice President, Regulatory Affairs and Quality Assurance
Elana Gazal	50	Vice President, Research and Development
Hadas Dreiher Horowitz	48	Vice President, Human Resources
Non-Employee Director		
Dr. Roger Pomerantz (1)(4)(5)	68	Chairman of the Board and Director
Dr. Abraham Havron (1)(3)(4)(5)	77	Director
Dr. Elan Penn (1)(2)(3)(4)(5)	73	Director
Joseph Zarzewsky (1)(2)(3)(4)	64	Director
Hugh Evans (1)(4)	58	Director
Alisa Lask (1)(2)(4)	54	Director

(1) Independent Director under the Nasdaq Listing Rules

(2) Member of the Compensation Committee

(3) Member of the Audit Committee

(4) Independent Director under Israeli Law

(5) Member of the Nominating and Corporate Governance Committee

Senior Management

Yehiel Tal has served as our chief executive officer since January 2010 and as a member of our board of directors since May 2022. Mr. Tal possesses over 30 years of management experience in the Israeli and American high-tech and biotechnology industries. Prior to joining us, Mr. Tal was the chief executive officer and co-founder of Regentis Biomaterials Ltd. Prior to that Mr. Tal served as vice-president of business development at ProChon BioTech Ltd. He has also served as vice president of marketing and business development at OrthoScan Technologies Ltd. and director of business development and business unit manager at Kulicke and Soffa Industries, Inc. In 2021, Mr. Tal was elected to the Board of Directors of the International Society for Biofabrication. Mr. Tal holds a Bachelor's and a Master's degree in mechanical engineering from the Technion, Israel Institute of Technology.

Eran Rotem has served as our chief financial officer since January 2012 and, since November 2017, also as our deputy CEO. Mr. Rotem possesses 30 years of broad financial and operational experience, primarily with biotechnology and industrial companies. Prior to joining us, Mr. Rotem served as the chief financial officer of Tefron Ltd., an industrial global company traded on both the Tel Aviv Stock Exchange (TASE:TFRN) and on the OTCBB (OTC:TFRFF) in the United States. Before Tefron, Mr. Rotem served as chief financial officer of Healthcare Technologies, Ltd. (NASDAQ:HCTL) and Gamida Ltd., a group of companies that specialize in the development, manufacturing, and marketing of clinical diagnostic test kits, as well as medical equipment and services to the biotechnology and high-tech industries. Prior to joining Healthcare Technologies, Ltd., Mr. Rotem served as a senior manager at Ernst & Young. Mr. Rotem holds a Bachelor's degree in Accounting and Business Administration from the Tel Aviv College of Management and is a Certified Public Accountant in Israel.

Oren Fahimipoor has been appointed as our vice president of operations effective as of April 2, 2023. Mr. Fahimipoor has more than 15 years of vast experience in leading complex operations in the biopharmaceutical industry. Prior to joining us, Mr. Fahimipoor was the business unit manager in Omrix Biopharmaceuticals, a Johnson and Johnson company, leading the Tel Hashomer plant operations end-to-end from 2019 to 2023 and the Ness Ziona Omrix site from 2018 to 2019. Mr. Fahimipoor also spent over a decade at Teva Pharmaceuticals from 2007 to 2018 where he held several leading positions in Teva's sterile production plant including leading sterile production and packaging of vials and syringes from 2012 to 2018 and as a researcher in biogenerics research and development from 2007 to 2012, developing four biosimilar products, including scale up processes and handling technical aspects of the drug development. Mr. Fahimipoor holds a BSc in Biotechnology Engineering from the Ben Gurion University and an MBA in Business Management from the Open University of Israel.

Dr. Philippe Bensimon has served as our vice president of regulatory affairs, quality assurance and clinical affairs since February 2011. Dr. Bensimon has over 30 years of experience in regulatory affairs, quality assurance and clinical affairs in international medical device companies. Prior to joining us Dr. Bensimon served for 14 years at InterVascular Datascope (now Maquet-Getinge Group), a manufacturer of long-term cardiovascular implants, as director of regulatory affairs, quality assurance, and clinical affairs. Dr. Bensimon also served for five years at 3M Medical as manager of regulatory affairs. Dr. Bensimon holds a PharmD degree from the University of Pharmacy, Marseille, France.

Elana Gazal has joined us as our Vice President of Research and Development as of November 2022. Dr. Gazal brings multidisciplinary experience in CMC, analytical chemistry and formulation development from Israeli and international companies engaging both pharmaceutical products and medical device. Prior to joining us, Dr. Gazal was the Head of Pharmaceutical Research in Neuroderm (now Mitsubishi Tanabe) leading their formulation development team and new LCM projects, taking part in the submission of ND0612 for PD patients. Prior to that, Dr. Gazal has worked at Waters IS as Application leader, in Foamix (now Wyne) developing their Minocycline foam and in Beckman Coulter (US) leading the prenatal markers area. Dr. Gazal holds a PhD in Organic Chemistry from HUJI.

Hadas Dreiher Horowitz has joined us as our vice president of human resources as of March 2021. Mrs. Dreiher Horowitz has over 16 years of experience in human resources. Prior to joining us, Mrs. Dreiher Horowitz served as Senior HR manager at Elbit Systems Ltd. from March 2019 to March 2021, and prior to that as HR manager at Teva Pharmaceutical Industries Ltd. from August 2013 to June 2018. Prior to that, Mrs. Dreiher Horowitz held various HR positions at Mul-T-Lock Technologies Ltd. and Job-Tov. Mrs. Dreiher Horowitz holds a Bachelor's degree in Behavioural Sciences from Ben-Gurion University, Israel and a Master's degree in Labor Studies from Tel Aviv University, Israel.

Non-Employee Directors

Dr. Roger Pomerantz has served as our Chairman of the board of directors since February 2020. Dr. Pomerantz served as Chairman and Chief Executive Officer of Contrafect Corporation (Nasdaq: CFRX) from April 2019 to November 2023. Prior to that, he served as Vice Chairman of Contrafect from May 2014 to April 2019. Previously, Dr. Pomerantz was a Venture Partner at Flagship Pioneering from 2014 through 2019. In addition, from November 2013 to December 2019, Dr. Pomerantz served as Chairman of the board of directors of Seres Therapeutics, Inc. (Nasdaq: MCRB), a biotechnology company, and as its President and Chief Executive Officer from June 2014 to January 2019. Prior to joining Seres, Dr. Pomerantz was Worldwide Head of Licensing & Acquisitions, Senior Vice President at Merck & Co., Inc., where he oversaw all licensing and acquisitions at Merck Research Laboratories, including external research, out-licensing regional deals, and academic alliances. Previously, he served as Senior Vice President and Global Franchise Head of Infectious Diseases at Merck. Prior to joining Merck, Dr. Pomerantz was Global Head of Infectious Diseases for J&J. Dr. Pomerantz has. Since July 2021 he served as Chairman of Indaptus Therapeutics (Nasdaq: INDP) and previously served on Intec Pharma's board of directors from 2018 until 2021. In addition, since May 2022 he served as Vice Chairman of Enlivex Therapeutics Ltd. (Nasdaq: ENLV), and was previously a member of the board of directors of Viracta (Nasdaq: VIRX) from June 2020 until December 2024, Rubius Therapeutics (Nasdaq: RUBY) from 2014 to 2019 and Evelo Therapeutics (Nasdaq: EVLO) from 2015 to 2016. Dr. Pomerantz earned his B.A. in biochemistry at the Johns Hopkins University and his M.D. at the Johns Hopkins School of Medicine. He completed his internal medicine internship and residency training, and his subspecialty clinical and research training in infectious diseases and virology at the Massachusetts General Hospital of Harvard Medical School. His post-doctoral research training in molecular retrovirology was obtained at both Harvard Medical School and the Whitehead Institute of the Massachusetts Institute of Technology (MIT). Dr. Pomerantz also served as the Chief Resident at the Massachusetts General Hospital. Following his medical-scientist training, he was an Endowed, Tenured Professor of Medicine and Molecular Pharmacology and Chairman of the Infectious Diseases Department of Thomas Jefferson University in Philadelphia. Dr. Pomerantz is an internationally recognized expert in HIV molecular pathogenesis and latency. He has developed ten approved infectious disease drugs in important diseases including HIV, HCV, tuberculosis, and Clostridium difficile infection.

Dr. Abraham (Avri) Havron has served on our board of directors since May 2016. Dr. Havron is a 41-year veteran of the biotech industry. Since 2005 and until 2014 when its acquisition by OPKO Health Inc. (NASDAQ: OPK) was completed. Dr. Havron was the Chief Executive Officer and a director of PROLOR Biotech Inc. (NYSE: PBTH). Between 1999 and 2003, Dr. Havron served as V.P. and Chief Technology Officer of Clal Biotechnology Industries Ltd. and prior to that for 12 years as V.P. Manufacturing and Process-Development of BioTechnology General Ltd. (now, a subsidiary of Ferring Pharmaceuticals). Dr. Havron was a member of the founding team of Interpharm Laboratories Ltd. (a subsidiary of Merck-Serono) - the first Israeli biotech company, where he served as Director of R&D from 1980 to 1987. During his managerial career Dr. Havron was directly involved in the multi-disciplinary development of many biopharmaceuticals, eight of which were approved and are marketed worldwide: Rebif (recombinant beta interferon), Biotropin (recombinant human growth hormone), Bio-Hep-B (3rd generation recombinant hepatitis B vaccine), Biolon and Euflexxa (ophthalmic and orthopedic devices containing bacteria derived hyaluronic acid), bio-similar recombinant Insulin and, Nexxobrid (debridement agent for severe burns), Somatrogan-recombinant long acting human growth hormone analog. Dr. Havron has been actively involved in establishing several biotech start-up companies among them Mediwound, Curetech, Prolor-Biotech, Polyheal, PamBio and Enlivex. He is also a member of the board of Enlivex Therapeutics Ltd. (NASDAQ: ENLV; TASE: ENLV), was the Chairman of Mediwound during 2001-2003 and later a member of its board from 2014 to 2017 (NASDAQ: MDWD) and from 2010 to 2018 was a member of the board of directors of Kamada Ltd. (NASDAQ: KMDA; TASE: KAMDA). Dr. Havron earned his PhD in chemistry from the Weizmann Institute of Science, and completed his post- doctorate at Harvard Medical School. Dr. Havron is also a board member of CollPlant Ltd., our wholly owned subsidiary.

Dr. Elan Penn has served on our board of directors since January 2018. Dr. Penn serves as chief executive officer and chairman of Penn Publishing Ltd., a private company based in Tel Aviv, Israel. Dr. Penn serves as external director of Dunietz Brothers Ltd. (TASE: DUNI:IT). Dr. Penn previously served as chairman of A.I. Conversation Systems Ltd. (TASE: AICS) from 2020 to 2024. From 2000 to 2001, Dr. Penn served as vice president of finance and administration of A.I. Research and Development Ltd. Dr. Penn served as chief executive officer of Sivan Computer Training Company Ltd. during the years 1998 through 2000. From 1992 to 2000, Dr. Penn served as vice president of finance and administration of Mashov Computers Ltd. From 1987 to 1991 and again from 1992 to 1997, Dr. Penn served as vice president of finance and administration of Magic Software Enterprises Ltd. (NASDAQ: MGIC) and, from 2005 to 2014, served as an external director of Magic Software. Dr. Penn previously served as a director of Telkoor Power Supplies Ltd. (TASE: TLCR) and Nexgen Biofuels Ltd. (formerly Healthcare Technologies Ltd) (OTC: NXGN). Dr. Penn holds a B.A. degree in Economics from the Hebrew University of Jerusalem and a Ph.D. in Management Science from the University of London. Dr. Penn is also a board member of CollPlant Ltd., our wholly owned subsidiary.

Joseph Zarzewsky has served on our board of directors since August 2019. Mr. Zarzewsky has served as the Vice President of Business Development at the Mitrelli Group, or Mitrelli, since June 2010. Mr. Zarzewsky has served as the Chairman of "SMAD", a joint venture between Mitrelli and the Harbin Government, China, since June 2011. Mr. Zarzewsky has also served as the Chairman of the Investment Committee of the Harbin Israel Fund since 2012, and as a member of the board of directors of Wize Pharma, Inc. (OTCQB: WIZP) since November 2017. He has also previously served as the Vice President of marketing at Clal Insurance Enterprises Holdings Ltd. (TASE: CLIS) and as the Vice President of Marketing for the Israel Postal Authority. In addition, Mr. Zarzewsky has served as a director of Excellence Underwriter House Ltd. since 2007. In 2008, he was appointed as the Honorary Economic Advisor of the Harbin Government, China. In addition, in June 2012, he was honored as an Honorary Citizen of Harbin, China. Mr. Zarzewsky holds an MA in Commercial Law from the University of Tel Aviv in collaboration with the University of California, Berkeley.

Hugh Evans has served on our board of directors since March 2021. Mr. Evans serves as a board member at Evolve, Additive Solutions, Amnovis and Advano. Previously Mr. Evans served as a board member of AquaVenture Holdings (NYSE: WAAS), which was acquired by Culligan International as well as FactoryFour which was acquired by Xometry. In 2019, Mr. Evans founded 3D Ventures Group, where he serves as a managing member. From 2013 to 2019, Mr. Evans served as Senior Vice President of Corporate Development & Digitization at 3D Systems (NYSE: DDD). Previously, from 1992 to 2013, he served as a portfolio manager at T. Rowe Price Associates (NASDAQ: TROW). Mr. Evans holds a BA in Psychology from the University of Virginia and an MBA from the Stanford Graduate School of Business.

Alisa Lask has served on our board of directors since August 2021. Ms. Lask is currently the CEO of Rion Aesthetics Inc., a company with commercial products in the exosome skincare space as well as development projects using regenerative exosomes in medical aesthetics. Ms. Lask is the former Vice President and General Manager of US Aesthetics at Galderma. Previously, she was a Senior Director of Global Strategic Marketing of Facial Aesthetics at Allergan. Earlier, she held strategic marketing positions at both Zimmer Biomet and Eli Lilly. Mrs. Lask received an M.B.A from the University of Michigan and has a B.S. in marketing from Miami University, Oxford, Ohio.

Advisory Boards

The members of our scientific and clinical advisory boards are appointed by our chief executive officer. Once nominated, the members of our advisory boards sign a standard letter of engagement. Most of the members of our advisory boards are not appointed for a specific term and their position may be terminated by either us or the member of the advisory board according to standard notice periods. The members of our advisory boards are all paid either daily or hourly fees for their services and are entitled to reimbursement of their expenses. Furthermore, several of the members of our advisory boards have been granted options due to their strategic role and years of service. The members of our advisory boards are as follows:

Advisory Board

Dr. Sachin M. Shridharani
Prof. Shay Soker
Prof. Ofer Levy, MD, MCh (Orth)

B. Compensation

Compensation of Senior Management and Directors

The following table presents in the aggregate all compensation we paid to all of our senior management and directors as a group for the year ended December 31, 2024. The table does not include any amounts we paid to reimburse any of such persons for costs incurred in providing us with services during this period.

	Salaries, fees, commissions, and bonuses(1) (thousand USD)	Equity-Based Compensation Granted(2) (thousand USD)
All senior management and directors as a group, consisting of 12 persons	2,700	1,167

(1) Salary includes cost of salary to the Company and ancillary benefits such as payments to the National Insurance Institute, advanced education funds, managers' insurance and pension funds; vacation pay; recuperations pay as mandated by Israeli law. This amount includes approximately $0.117 million set aside or accrued to provide pension, severance, retirement, vacation or similar benefits or expenses.

(2) Consists of amounts recognized as share-based compensation expense for the year ended December 31, 2024. Assumptions and key variables used in the calculation of such amounts are discussed in Note 8 of our financial statements.

In accordance with the Companies Law, the following table presents information regarding compensation of our five most highly paid office holders, namely our Chief Executive Officer, Deputy CEO and Chief Financial Officer, Vice President Regulatory Affairs and Quality Assurance, Vice President Research and Development, and Vice President Operations, during the year ended December 31, 2024.

Name and Position(1)	Salary Cost (2) (thousand USD)	Cash Incentives (thousand USD)(3)	Value of Options Granted(4) (thousand USD)	Total (thousand US dollar)
Yehiel Tal, CEO	540	202	269	1,011
Eran Rotem, Deputy CEO & CFO	422	112	218	752
Philippe Bensimon, VP RA& QA	242	41	98	381
Elana Gazal, VP Research and Development	258	30	77	365
Oren Fahimipoor, VP Operations	248	45	139	432

(1) All such officers are employed on a full-time (100%) basis.

(2) Salary includes cost of salary to the Company and ancillary benefits such as payments to the National Insurance Institute, advanced education funds, managers' insurance and pension funds; vacation pay; recuperations pay as mandated by Israeli law.

(3) Amounts reported in this column refer to the cash incentives with respect to 2024, which are expected to be paid later in 2025 subject to achievement of a certain contingency. Such amounts exclude cash incentives paid during 2024 which were provided in the Company's financial statements for previous years.

(4) Represents the share-based compensation expenses recorded in the Company's consolidated financial statements for the year ended December 31, 2024, based on the equity fair value on the grant date, calculated in accordance with accounting guidance for share-based compensation. For a discussion on the assumptions used in reaching this valuation, see Note 8 to our consolidated financial statements for the year ended December 31, 2024 for more information.

Compensation of Directors

Our directors (other than the Chairman) are entitled to an annual fee of $25,000 and a per meeting participation fee of $800, and any applicable VAT as well as reimbursement of expenses, including meeting participation expenses, reimbursement of business travel including a daily stipend when traveling and accommodation expenses.

Our Chairman is entitled to a monthly consulting fee of $14,584 plus applicable VAT as well as reimbursement, against receipts, for out-of-pocket business expenses, reasonably and necessarily incurred by him relating to the provision of his services, provided that our prior approval for such expense has been obtained.

The members of our board of directors are also entitled to a letter of indemnification and exemption, in the Company's standard form, and to coverage under our D&O insurance policies, as renewed from time to time.

On October 10, 2023, our general meeting of shareholders approved, following approval of our compensation committee and board of directors, and as part of a broader repricing decision applying to our employees and officers, the repricing of the exercise price of option to purchase ordinary shares, previously granted to our directors and our CEO (who also serves as a director on our board of directors), whose exercise price was $9.12-$15.2, such that their new exercise price will be $6.39, which represents the average of the closing price of our ordinary shares during the 30 days preceding the board of directors' decision on the repricing.

On April 3, 2024, the board of directors (following the approval of the compensation committee with respect to the Company's directors and officers) approved to extend the expiry date of 337,464 options exercisable into 337,464 ordinary shares that were previously granted to some of our employees and directors, from an expiry date ranging between December 2024 and July 2025, by an additional three years, such that the expiry dates will range between December 2027 and July 2028. Out of the said options, 126,800 options exercisable into 126,800 ordinary shares are held by some of the Company's directors and by its CEO (who also serves as a director on the board of directors), and as such, the extension of the expiry dates of these options was subject to the receipt of shareholders' approval by the required majorities under applicable law, which approval was obtained on September 25, 2024 at the Company's general meeting of shareholders.

Employment and Services Agreements with Senior Management

We have entered into written employment agreements with each of our executive officers. These agreements provide for notice periods of varying duration for termination of the agreement by us or by the relevant executive officer, during which time the executive officer will continue to receive base salary and benefits. These agreements also contain customary provisions regarding noncompetition, confidentiality of information and assignment of inventions. However, the enforceability of the noncompetition provisions may be limited under applicable law. In addition, from time to time we grant our senior managers options to purchase ordinary shares under our equity compensation plans. For information on our equity compensation plans, please see Item 6.E – Share Ownership.

On July 18, 2023, our general meeting of shareholders approved the adoption and grant of a new letter of indemnification for the Company's current and future directors and officers. For information on exemption and indemnification letters granted to our directors and officers, please see "C. Board Practices – Exemption, Insurance and Indemnification of Directors and Officers".

C. Board Practices

Board of Directors

Under the Companies Law, the overseeing of the management of our business is vested in our board of directors. Our board of directors may exercise all powers and may take all actions that are not specifically granted to our shareholders or to management. Our officers are responsible for our day-to-day management and have individual responsibilities established by our board of directors and specified in their specific employment agreements. Our chief executive officer is appointed by, and serves at the discretion of, our board of directors, subject to the employment agreement that we have entered into with him. All other officers are appointed by our chief executive officer with the prior review of our board of directors and compensation committee, and are subject to the terms of any applicable employment agreements that we may enter into with them.

Under our articles of association, our board of directors must consist of at least three and not more than twelve directors, including at least two external directors, but allows us, subject to and in accordance with the provisions of any law, to determine that the provisions relating to external directors (including the obligation to appoint external directors) shall not apply to us.

On December 20, 2021, our board of directors determined that in light of our current shareholding structure, which no longer supports the claim that we have a controlling shareholder, it was decided to reinstate the relief provided under an exemption, or the Exemption, that provides relief for Israeli companies whose shares are listed on certain stock exchanges outside of Israel (including the Nasdaq Global Market) with no controlling shareholder from being required to appoint external directors so long as such companies satisfy the requirements of the foreign laws in the listing jurisdiction outside of Israel which apply to companies incorporated in such jurisdiction, in respect of the appointment of independent directors and the composition of the audit committee and compensation committee, adopted by our board of directors in November 2018. As such, our then external directors, were no longer classified as external directors, as of which date they continued to serve on our board of directors as independent directors.

Currently our board of directors consists of six non-employee directors, all of who are elected annually at the general meeting of our shareholders by a vote of the holders of a majority of the voting power present and voting, in person or by proxy, at that meeting.

We have two types of directors: independent directors and "regular" directors. For purposes of complying with the Nasdaq Listing Rules to list the Company's ordinary shares on the Nasdaq Global Market, our board of directors is comprised of six independent directors and one regular director.

Our board of directors has determined that all of our non-employee directors are independent under such rules.

Under the Companies Law any shareholder holding at least 1% of our outstanding voting power may submit to our board of directors a request to add an item to the agenda of a general meeting that is due to convene, provided that such item is suitable to be discussed at the general meeting. Accordingly, a shareholder may propose to nominate one or more persons for election as directors at a general meeting by delivering a written notice of such shareholder's intent to make such nomination or nominations, setting forth all of the details and information as required to be provided by our amended and restated articles of association and regulations promulgated under the Companies law.

In addition, our articles of association allow our board of directors to appoint additional director or directors who shall remain in office until the next annual shareholders' meeting, provided that the board of directors must consist of no more than 12 directors. In addition, our articles of association allow our board of directors to appoint alternate directors to fill vacancies on our board of directors, for a term of office equal to the remaining period of the term of office of the director(s) whose office(s) have been vacated.

Under the Companies Law, our board of directors must determine the minimum number of directors who are required to have accounting and financial expertise. In determining the number of directors required to have such expertise, our board of directors must consider, among other things, the type and size of the company and the scope and complexity of its operations. Our board of directors has determined that the minimum number of directors who are required to have accounting and financial expertise is one.

External Directors

Under the Companies Law, companies incorporated under the laws of the State of Israel that are "public companies", including companies with shares listed on the Nasdaq, are required to appoint at least two external directors. The external directors must meet strict independence criteria to ensure that they are unaffiliated with the company and any controlling shareholder. At least one of the external directors is required to have financial and accounting expertise, and the other external director must have either financial and accounting expertise or professional qualifications, as defined in the regulations promulgated under the Companies Law. The Companies Law also provides that the external directors must serve on both the audit committee and the compensation committee, that the audit committee and the compensation committee must both be chaired by an external director, and that at least one external director must serve on every board committee authorized to exercise powers of the board of directors. Additional rules govern the term and compensation of external directors. Pursuant to regulations promulgated under the Companies Law, companies with shares traded on certain U.S. stock exchanges, including the Nasdaq, may, subject to certain conditions, adopt an exemption, or, the Exemption, from the Companies Law requirements to appoint external directors and related Companies Law rules concerning the composition of the audit committee and compensation committee of the Board of Directors. In accordance with these regulations, we have elected to adopt the Exemption, which exempts us from the Companies Law requirement to appoint external directors and related Companies Law rules concerning the composition of the audit committee and compensation committee of the Board of Directors.

For further information on our decision to adopt the Exemption, please see C. Board Practices – Board of Directors.

Role of Board of Directors in Risk Oversight Process

Risk assessment and oversight are an integral part of our governance and management processes. Our board of directors encourages management to promote a culture that incorporates risk management into our corporate strategy and day-to-day business operations. Management discusses strategic and operational risks at regular management meetings and conducts specific strategic planning and review sessions during the year that include a focused discussion and analysis of the risks facing us. Throughout the year, senior management reviews these risks with the board of directors at regular board meetings as part of management presentations that focus on particular business functions, operations or strategies, and presents the steps taken by management to mitigate or eliminate such risks.

Leadership Structure of the Board of Directors

In accordance with the Companies Law and our articles of association, our board of directors is required to appoint one of its members to serve as chairman of the board of directors. Our board of directors has appointed Dr. Roger Pomerantz to serve as chairman of the board of directors.

Committees of the Board of Directors

Currently, our board of directors has three permanent committees: an audit committee, a compensation committee, and a nominating and corporate governance committee.

Audit Committee

Under the Companies Law, the board of directors of a public company must appoint an audit committee that will comply with certain composition requirements, subject to the possibility of a company to opt out of certain Companies Law requirements under certain circumstances, as we have. Under the Nasdaq Listing Rules, we are required to maintain an audit committee consisting of at least three independent directors, all of whom are financially literate and at least one of whom has accounting or related financial management expertise.

Accordingly, our audit committee consists of Dr. Avraham Havron, Dr. Elan Penn and Joseph Zarzewsky, each of whom meets the requirements for independence under the rules of the Nasdaq and the applicable rules and regulations of the SEC. Each member of our audit committee also meets the financial literacy requirements in the rules of the Nasdaq and the applicable rules and regulations of the SEC. In addition, our board of directors has determined that Dr. Elan Penn is an audit committee financial expert within the meaning of Item 407(d) of Regulation S-K under the Securities Act.

Our board of directors has adopted a new audit committee charter in November 2023, setting forth the responsibilities of the audit committee consistent with the rules of the SEC and the Nasdaq Listing Rules as well as the requirements for such committee under the Companies Law, including the following:

- providing oversight of our accounting and financial reporting process and the audits of our financial statements;
- assisting our board of directors in its oversight of (i) the quality and integrity of our financial statements and other published financial information, (ii) our compliance with applicable financial and accounting related standards, rules and regulations, (iii) the selection, retention and termination, subject to shareholder approval, of our independent auditor, (iv) the pre-approval of all audit, audit-related and all permitted non-audit services, if any, by our independent auditor, and the compensation therefor and (v) our internal controls over financial reporting;
- determining whether there are delinquencies in our business management practices, including in consultation with our internal auditor or independent auditor, and making recommendations to our board of directors to improve such practices;
- determining whether to approve certain related party transactions or transactions in which a board member or other office holder has a personal interest and whether such transaction is material to us;
- preparing any report that the rules of the SEC require (if we are then subject to the U.S. proxy rules) to be included, or that we otherwise elect to include, in our annual proxy statement;
- providing the board of directors with the results of its monitoring and recommendations derived from the foregoing; and
- fulfilling any other duties of the audit committee as shall be required under the Companies Law.

Our audit committee provides assistance to our board of directors in fulfilling its legal and fiduciary obligations in matters involving our accounting, auditing, financial reporting, internal control, and legal compliance functions by pre-approving the services performed by our independent accountants and reviewing their reports regarding our accounting practices and systems of internal control over financial reporting. Our audit committee also oversees the audit efforts of our independent accountants and takes those actions that it deems necessary to satisfy itself that the accountants are independent of management.

Under the Companies Law, our audit committee is mainly responsible for:

- determining whether there are deficiencies in our business management practices, including in consultation with our internal auditor or the independent auditor, and making recommendations to the board of directors to improve such practices;
- determining whether certain acts of an office holder not in accordance with his or her fiduciary duty owed to the Company are extraordinary or material and to approve such acts and certain related party transactions (including transactions in which an office holder has a personal interest) and whether such transaction is extraordinary or material under the Companies Law (see "—Approval of Related Party Transactions Under Israeli Law" below);
- determining procedures for a competitive process, or other procedures, before approving related party transactions with controlling shareholders, even if such transactions are deemed by the audit committee not to be extraordinary transactions. This process is to be supervised by the audit committee, or any person authorized for such supervision, or via any other method approved by the audit committee;
- determining whether or not to approve acts or transactions that require the audit committee's approval pursuant to the Companies Law.
- determining the approval process for transactions that are not negligible, as well as determine which types of transactions would require the approval of the audit committee. Non-negligible transactions are defined as related party transactions with a controlling shareholder, or in which the controlling shareholder has a personal interest, that the audit committee classified as non-extraordinary transactions and which have also been classified by the audit committee as non-negligible transactions;

- where the board of directors approves the work plan of the internal auditor, to examine such work plan before its submission to the board and propose amendments thereto;

- examining our internal controls and internal auditor's performance, including whether the internal auditor has sufficient resources and tools to dispose of its responsibilities, considering, *inter alia*, the company's specific needs and its size;

- examining the scope of our auditor's work and compensation and submitting a recommendation with respect thereto to our board of directors or shareholders, depending on which of them is considering the appointment of our auditor; and

- establishing procedures for the handling of employees' complaints as to deficiencies in the management of our business and the protection to be provided to such employees.

Our audit committee may not approve any actions requiring its approval (see "—Approval of Related Party Transactions Under Israeli Law" below), unless at the time of approval a majority of the committee's members are present.

Compensation Committee

Under the Companies Law, the board of directors of a public company must appoint a compensation committee. The Companies Law provides composition requirements applicable to a compensation committee, unless a company elects to opt-out of certain Companies Law requirements, under certain circumstances, as we have. Our compensation committee consists of Dr. Elan Penn, Alisa Lask and Joseph Zarzewsky, each of whom meets the requirements for independence under the rules of the Nasdaq Global Market and the applicable rules and regulations of the SEC.

The duties of the compensation committee include the recommendation to the company's board of directors of a policy regarding the terms of engagement of office holders, to which we refer as a compensation policy, and to examine the need to update the compensation policy. This policy must be adopted by the company's board of directors, after considering the recommendations of the compensation committee, and must be approved by the company's shareholders by a special majority, which we refer to as a Special Majority for Compensation. This Special Majority for Compensation requires shareholder approval by a majority vote of the shares present and voting at a meeting of shareholders called for such purpose, provided that either: (i) such majority includes at least a majority of the shares held by all shareholders who are not controlling shareholders and do not have a personal interest in such compensation arrangement; or (ii) the total number of shares of non-controlling shareholders and shareholders who do not have a personal interest in the compensation arrangement and who vote against the arrangement does not exceed 2% of the company's aggregate voting rights. Under special circumstances, the board of directors may approve the compensation policy despite the objection of the shareholders on the condition that the compensation committee (or the audit committee acting in lieu of a compensation committee pursuant to the Companies Law) and then the board of directors decide, on the basis of detailed arguments and after discussing the compensation policy once again, that approval of the compensation policy, despite the objection of the meeting of shareholders, is for the benefit of the company. Our current compensation policy was approved by our shareholders on May 2, 2022 by the required Special Majority for Compensation, and is in effect for a period of three years from its date of original approval. The compensation policy does not, by nature, grant any rights to our directors or officers. The compensation policy includes both long-term and short-term compensation elements and is to be reviewed from time to time by our compensation committee and our board of directors, according to the requirements of the Companies Law. On July 18, 2023, our shareholders approved, by the required Special Majority for Compensation, an amendment to our compensation policy with respect to the adoption of a new clawback policy intended to comply with the clawback-related listing standards of the Nasdaq Stock Market and the Companies Law, which took effect upon the effective date of the Nasdaq listing rule (*i.e.*, December 1, 2023).

Our compensation policy serves as the basis for decisions concerning the financial terms of employment or engagement of office holders, including exemption, insurance, indemnification or any monetary payment or obligation of payment with respect to employment or engagement. According to the Companies Law, the compensation policy must be approved (or reapproved) not longer than every three years and relate to certain factors, including advancement of the company's objectives, the company's business plan and its long-term strategy, and creation of appropriate incentives for office holders. It must also consider, among other things, the company's risk management, size, and nature of its operations. With respect to the compensation terms that include variable compensation, the compensation policy must also consider the officer holders' contribution to meeting the Company's objectives and the creation of profit, all with a long-term view and according to the office holder's position. The compensation policy must furthermore consider the following additional factors:

- the knowledge, skills, expertise, and accomplishments of the relevant office holder;
- the office holder's roles and responsibilities and prior compensation agreements with him or her;
- the ratio between the terms offered and the cost of employment of the other employees of the company, including those employed through manpower companies, and in particular the ratio between the average salary and the median salary of such employees;
- the impact of disparities in salary upon work relationships in the company;
- the possibility of reducing variable compensation at the discretion of the board of directors;
- the possibility of capping the exercise value of non-cash variable equity-based compensation; and
- as to severance compensation, the period of service of the office holder, the terms of his or her compensation during such service period, the company's performance during that period of service, the person's contributions towards the company's achievement of its objectives and the maximization of its profits, and the circumstances under which the person is leaving the company.

The compensation policy must also include the following principles:

- the linkage between variable compensation and long-term performance and measurable criteria.
- the ratio between variable and fixed compensation, and the ceiling for the value of variable compensation at the time of the payment (or with respect to variable equity compensation that is not paid for in cash, a ceiling for their value on the grant date);
- the conditions under which an office holder would be required to repay compensation paid to him or her if it was later shown that the data upon which such compensation was based was inaccurate and was required to be restated in the company's financial statements;
- the minimum holding or vesting period for variable, equity-based compensation with a view to long-term incentives; and
- maximum limits for severance compensation.

Our board of directors has adopted a new compensation committee charter in November 2023, setting forth the responsibilities of the committee, which include:

- reviewing and setting or making recommendations to our board of directors regarding the compensation of our CEO and the other directors and officers;
- reviewing the compensation disclosure included in Item 6 of our annual reports;
- recommending to our board of directors, for its approval, a compensation policy, in accordance with the requirements of the Companies Law and any other compensation policies, incentive-based compensation plans and equity-based plans as well as any claw-back recovery provisions, or collectively, the Compensation Plans and Policies;

- overseeing the development and implementation of the Compensation Plans and Policies that are appropriate for the Company in light of all relevant circumstances and recommending to our board of directors any amendments or modifications to the Compensation Plans and Policies that the compensation committee deems appropriate, including the extension of Compensation Plans and Policies as required by the Companies Law;

- determining whether to approve transactions concerning the terms of engagement and employment of the our CEO, other officers and directors that require the approval of the compensation committee under the Companies Law or the Compensation Plans and Policies;

- taking any further actions as the compensation committee is required or allowed to under the Companies Law or the Compensation Plans and Policies; and,

- reviewing and approving, or, if required by law or the Compensation Plans and Policies, approve and recommend for approval by our board of directors, grants and awards under our equity incentive plans.

Nominating and Corporate Governance Committee

Our nominating and corporate governance committee consists of Dr. Roger Pomerantz, Dr. Abraham Havron, and Dr. Elan Penn. Each of the members of our nominating and corporate governance committee is independent under the listing requirements of the Nasdaq Global Market.

Our board of directors has adopted a new nominating and governance committee charter in November 2023, setting forth the responsibilities of the nominating and governance committee, which include:

- examining the qualifications, skills and experiences of potential director candidates;

- recommending to our board of directors, for its approval, the criteria for nominating board members and guidelines for the structure of the board of directors, to be used by the committee in recommending directors and by the board of directors in nominating directors;

- reviewing the board committee structure and periodically recommending to the board of directors, for its approval, directors to serve as members of each committee;

- reviewing and assessing the adequacy of our approach to corporate governance and any such corporate governance guidelines adopted by our board of directors and recommending any proposed changes to the board of directors for approval;

- making recommendations to our board of directors regarding governance matters, including our articles of association and the charters of our other committees. Our board of directors may refer to the committee other matters and questions relating to corporate governance and nomination as our board of directors may from time to time see fit; and,

- reporting regularly to our board of directors regarding the committee's activities.

Internal Auditor

Under the Companies Law, the board of directors of a public company must appoint an internal auditor based on the recommendation of the audit committee. The role of the internal auditor is to examine, among other things, our compliance with applicable law and orderly business procedures. The audit committee is required to oversee the activities and to assess the performance of the internal auditor as well as to review the internal auditor's work plan.

An internal auditor may not be:

- a person (or a relative of a person) who holds 5% or more of the company's outstanding shares or voting rights;
- a person (or a relative of a person) who has the power to appoint a director or the general manager of the company;
- an office holder or director (or a relative of an officer or director) of the company; or
- a member of the company's independent accounting firm, or anyone on its behalf.

Ms. Dana Gottesman Erlich, has been serving as our Internal Auditor since November 2013. Ms. Gottesman Erlich is a CPA, CIA, MA, Partner in the Risk Advisory Services (RAS) Group at the accounting firm of BDO Ziv Haft. Ms. Gottesman Erlich has more than 10 years of experience in the provision of internal audit and risk management consulting services to public and private companies, government agencies, municipalities, non-profit organizations, and more. Ms. Gottesman Erlich specializes in the analysis and specification of work procedures and their assimilation in the organization, the internal audit of work procedures in different organizations, including the performance of risk surveys and fraud and embezzlement surveys. Ms. Gottesman Erlich holds a BA in Accounting and Business Administration and an MA in Internal Audit and Public Administration. Ms. Gottesman Erlich's nomination satisfies the requirements of the Companies Law.

Approval of Related Party Transactions under Israeli Law

Fiduciary Duties of Directors and Officers

The Companies Law imposes a duty of care and a fiduciary duty on all office holders of a company. Each person listed in the table under "Management—Senior Management and Directors" is an office holder under the Companies Law.

The duty of care requires an office holder to act with the degree of proficiency with which a reasonable office holder in the same position would have acted under the same circumstances. The fiduciary duty requires that an office holder act in good faith and in the best interests of the company.

The duty of care includes a duty to use reasonable means to obtain:

- information on the advisability of a given action brought for his or her approval or performed by virtue of his or her position; and
- all other important information pertaining to these actions.

The fiduciary duty includes a duty to:

- refrain from any act involving a conflict of interest between the performance of his or her duties to the company and his or her other duties or personal affairs;
- refrain from any activity that is competitive with the company;
- refrain from exploiting any business opportunity of the company to receive a personal gain for himself or herself or others; and
- disclose to the company any information or documents relating to the company's affairs which the office holder received as a result of his or her position as an office holder.

Disclosure of Personal Interests of an Office Holder and Approval of Certain Transactions

The Companies Law requires that an office holder promptly disclose to the company any personal interest that he or she may be aware of and all related material information or documents concerning any existing or proposed transaction by the company. An interested office holder's disclosure must be made promptly and, in any event, no later than the first meeting of the board of directors at which the transaction is considered. An office holder is not obliged to disclose a personal interest if it derives solely from the personal interest of his or her relative in a transaction that is not considered as an extraordinary transaction.

A "personal interest" is defined under the Companies Law to include a personal interest of any person in an act or transaction of a company, including the personal interest of such person's relative or of a corporate body in which such person or a relative of such person is a 5% or greater shareholder, director, or general manager or in which he or she has the right to appoint at least one director or the general manager, but excluding a personal interest solely stemming from one's ownership of shares in the company.

A personal interest furthermore includes the personal interest of a person for whom the office holder holds a voting proxy or the personal interest of the office holder with respect to his or her vote on behalf of a person for whom he or she holds a proxy even if such shareholder has no personal interest in the matter.

Under the Companies Law, an extraordinary transaction is defined as any of the following:

- a transaction other than in our ordinary course of business;
- a transaction that is not on market terms; or
- a transaction that may have a material impact on the company's profitability, assets, or liabilities.

Under the Companies Law, the audit committee is the organ responsible for classifying a transaction with an officer holder, or in which an officer holder has a personal interest, as an extraordinary transaction, and may make such classification regarding certain types of actions or transactions based on pre-determined criteria once a year. If it is determined that an office holder has a personal interest in a transaction which is not an extraordinary transaction, approval by the board of directors is required for such transaction, unless the company's articles of association provide for a different method of approval. An extraordinary transaction in which an office holder has a personal interest requires approval first by the company's audit committee and subsequently by the board of directors. In general, the compensation of, or an undertaking to indemnify or insure, an office holder who is not a director requires approval first by the company's compensation committee, then by the company's board of directors, and, if such compensation arrangement or an undertaking to indemnify or insure is inconsistent with the company's stated compensation policy or if the office holder is the chief executive officer (apart from a number of specific exceptions), then such arrangement is subject to shareholders' approval by the Special Majority for Compensation. Arrangements regarding the compensation, exculpation, indemnification, or insurance of a director require the approval of the compensation committee, board of directors, and shareholders by ordinary majority, in that order, and under certain circumstances, a special majority approval.

Generally, a person who has a personal interest in a matter which is being considered at a meeting of the board of directors or the audit committee may not be present at such a meeting or vote on that matter unless the chairman of the relevant committee or board of directors (as applicable) determines that he or she should be present in order to present the transaction that is subject to approval. If a majority of the members of the audit committee or the board of directors (as applicable) have a personal interest in the approval of a transaction, then all directors may participate in discussions of the audit committee or the board of directors (as applicable) on such transaction and the voting on approval thereof, but shareholder approval is also required for such transaction (except in cases where specific reliefs are applied, or in cases where the said transaction is a non-extraordinary transaction with an officer holder or in which an officer holder has a personal interest).

Disclosure of Personal Interests of Controlling Shareholders and Approval of Certain Transactions

Under Israeli Law, the term "controlling shareholder" means a shareholder with the ability to direct the activities of our company, other than by virtue of being an officer or director. A shareholder is presumed to be a controlling shareholder if the shareholder holds 50% or more of the voting rights in a company or has the right to appoint at least half of the directors of the company or its general manager. For the purpose of approving transactions with related parties, the definition of controlling shareholder also includes any shareholder that holds 25% or more of the voting rights in a public company if no other shareholder holds more than 50% of the voting rights in the company. For purposes of determining the holding percentage stated above, two or more shareholders who have a personal interest in a transaction that is brought for the company's approval are deemed as joint holders.

Pursuant to Israeli law, the disclosure requirements regarding personal interests that apply to directors and officers also apply to a controlling shareholder of a public company. In the context of a transaction involving a shareholder of the company, as mentioned above, a controlling shareholder also includes a shareholder who holds 25% or more of the voting rights in the company if no other shareholder holds more than 50% of the voting rights in the company. Generally, the approval of the audit committee or compensation committee, the board of directors, and a special majority, in that order, is required for: (i) extraordinary transactions with a controlling shareholder or in which a controlling shareholder has a personal interest, including any private placements in which a controlling shareholder has a personal interest; (ii) the engagement with a controlling shareholder or his or her relative, directly or indirectly, for the provision of services to the company; (iii) the terms of engagement and compensation of a controlling shareholder or his or her relative who is an office holder; or (iv) the employment of a controlling shareholder or his or her relative by the company. For this purpose, a "special majority" approval requires shareholder approval by a majority vote of the shares present and voting at a meeting of shareholders called for such purpose, provided that either: (a) such majority includes at least a majority of the shares held by all shareholders who do not have a personal interest in the approval of such item; or (b) the total number of shares of non-controlling shareholders and shareholders who do not have a personal interest in the approval of such item and who vote against the arrangement does not exceed 2% of the company's aggregate voting rights.

To the extent that any such transaction with a controlling shareholder is for a period extending beyond three years, approval is required once every three years, unless, with respect to certain transactions, the audit committee determines that the duration of the transaction is reasonable given the circumstances related thereto.

Arrangements regarding the compensation, exculpation, indemnification, or insurance of a controlling shareholder in his or her capacity as an office holder require the approval of the compensation committee and board of directors, and, in general, approval by a special majority of shareholders.

Pursuant to regulations promulgated under the Companies Law, certain transactions with a controlling shareholder or his or her relative, or with directors, that would otherwise require approval of a company's shareholders may be exempt from shareholder approval upon certain determinations of the audit committee or compensation committee and board of directors.

Shareholders' Duties

Under the Companies Law, a shareholder has a duty to act in good faith and in a customary manner toward the company and other shareholders and to refrain from abusing his or her power in the company, including, among other things, in voting at general meetings of shareholders and class meetings of shareholders with respect to the following matters:

- an amendment of the articles of association or memorandum of association of the company;
- an increase in the company's authorized share capital;
- a merger; or
- the approval of related party transactions and acts of office holders that require shareholder approval.

A shareholder also has a general duty to refrain from discriminating against other shareholders. In addition, certain shareholders have a duty of fairness toward the company. These shareholders include any controlling shareholder, any shareholder who knows that he or she has the power to determine the outcome of a shareholder vote and any shareholder who has the power to appoint or to prevent the appointment of an office holder of the company or other power. The Companies Law does not define the substance of the duty of fairness, except to state that the remedies generally available upon a breach of contract will also apply in the event of a breach of the duty to act with fairness.

Exemption, Insurance and Indemnification of Directors and Officers

Under the Companies Law, a company may not exempt an office holder from liability for a breach of the duty of loyalty. An Israeli company may exculpate an office holder in advance from liability to the company, in whole or in part, for damages caused to the company as a result of a breach of duty of care but only if a provision authorizing such exemption is included in its articles of association. Our articles of association include such a provision. A company may not exempt a director from liability arising out of a prohibited dividend or distribution to shareholders.

Under the Companies Law, an Israeli company may indemnify an office holder with respect to the following liabilities and expenses incurred for acts performed as an office holder, either in advance of an event or following an event, provided a provision authorizing such indemnification is contained in its articles of association:

- financial liability imposed on him or her in favor of another person pursuant to a judgment, including a settlement or arbitrator's award approved by a court. However, if an undertaking to indemnify an office holder with respect to such liability is provided in advance, then such an undertaking must be limited to events which, in the opinion of the board of directors, can be foreseen based on the company's activities when the undertaking to indemnify is given, and to an amount or according to criteria determined by the board of directors as reasonable under the circumstances, and such undertaking must detail the abovementioned foreseen events and amount or criteria;

- reasonable litigation expenses, including attorneys' fees, incurred by the office holder: (i) as a result of an investigation or proceeding instituted against him or her by an authority authorized to conduct such investigation or proceeding, provided that (a) no indictment was filed against such office holder as a result of such investigation or proceeding and (b) no financial liability was imposed upon him or her as a substitute for the criminal proceeding as a result of such investigation or proceeding or, if such financial liability was imposed, it was imposed with respect to an offense that does not require proof of criminal intent; and (ii) in connection with a monetary sanction;

- Expenses incurred in connection with an Administrative Proceeding that has been conducted in his case, including reasonable litigation costs, covering also legal fees.

  "**Administrative Proceeding**" - a proceeding to impose a financial sanction according to Article D of Chapter Four of Part 9 of the Companies Law as amended from time to time; as well as proceeding according to Chapter G1 of the Economic Competition Law, 5748-1988, as amended from time to time; as well as any additional administrative proceeding whereby, by law (and subject to that law) an indemnity may be granted in respect of payments related thereto or expenses incurred in connection therewith; and,

- reasonable litigation expenses, including attorneys' fees, incurred by the office holder or imposed by a court in proceedings instituted against him or her by the company, on its behalf, or by a third party or in connection with criminal proceedings in which the office holder was acquitted or as a result of a conviction for an offense that does not require proof of criminal intent.

Under the Companies Law, a company may insure an office holder against the following liabilities incurred for acts performed as an office holder if, and to the extent, provided in the company's articles of association:

- a breach of duty of care to the company or to a third party, including a breach arising out of the negligent conduct of the office holder;

- a breach of fiduciary duty to the company, to the extent that the office holder acted in good faith and had a reasonable basis to believe that the act would not prejudice the company;

- a monetary liability imposed on the office holder in favor of a third party; and

- expenses incurred by an office holder in connection with an administrative procedure, including reasonable litigation expenses and reasonable attorneys' fees.

Under the Companies Law, a company may not indemnify or insure an office holder against any of the following:

- a breach of fiduciary duty, except for indemnification and insurance for a breach of the fiduciary duty to the company and to the extent that the office holder acted in good faith and had a reasonable basis to believe that the act would not prejudice the company;
- a breach of duty of care committed intentionally or recklessly, excluding a breach arising out of the negligent conduct of the office holder;
- an act or omission committed with intent to derive illegal personal benefit; or
- a fine or forfeit levied against the office holder.

Under the Companies Law, exemption, indemnification, and insurance of office holders in a public company must be approved by the compensation committee and the board of directors and, with respect to certain office holders or under certain circumstances, by the shareholders.

Our articles of association and compensation policy allow us to exempt, indemnify, and insure our office holders according to applicable law.

We have obtained directors' and officers' liability insurance for the benefit of our office holders and intend to continue to maintain such coverage and pay all premiums thereunder to the fullest extent permitted by the Companies Law. In addition, we have entered into agreements with each of our current office holders undertaking to indemnify them to the fullest extent permitted by the Companies Law and our articles of association, to the extent that these liabilities are not covered by insurance. On July 18, 2023, our shareholders approved, following the approvals of our compensation committee and board of directors, the adoption and grant of a new letter of indemnification to our existing and future directors and officers. For information regarding our letters of exemption and indemnification, see Item 7B - Insurance, Exemption, and Indemnification Agreements.

In the opinion of the Securities and Exchange Commission, indemnification of directors and office holders for liabilities arising under the Securities Act, however, is against public policy and therefore unenforceable.

D. Employees.

See "Item 4.B. Business Overview—Employees."

E. Share Ownership.

See "Item 7.A. Major Shareholders" below.

Share Incentive Plan and Share Award Plan

In May 2010, we adopted the 2010 Plan, which was extended on March 26, 2020 by our board of directors, in accordance with the compensation committee's recommendation, for an additional period of ten (10) years. The 2010 Plan allows us to grant options to purchase our ordinary shares to our employees, officers, directors and consultants. As of March 15, 2025, our employees, officers, directors and consultants hold an aggregate of options to purchase 1,699,693 ordinary shares, under the 2010 Plan. Since 2008, options to purchase an aggregate of 272,819ordinary shares had been exercised and transferred to the beneficial holders (or to a trustee who holds them to their benefit).

In April 2024, we adopted the 2024 Plan, an equity share-based incentive plan. The 2024 Plan allows us to grant several equity-based awards, including options, shares, restricted shares, restricted share units, stock appreciation rights, performance units, performance shares and other stock or cash awards. The purpose of the 2024 Plan is to advance the interests of the Company and its shareholders by attracting and retaining the best available personnel for positions of substantial responsibility, providing additional incentive to employees, officers, directors, and consultants and promoting a close identity of interests between those individuals and the Company. The 2024 Plan shall be in effect for a term of ten (10) years from the date of adoption, *i.e.*, until April 2034. As of March 15, 2025, our employees, officers, directors and consultants hold an aggregate of 34,000 options to purchase ordinary shares, and an aggregate of 426,000 restricted share units (RSU), under the 2024 Plan.

The 2010 Plan and the 2024 Plan shall collectively be referred to as the Plans, while the awards that may be granted pursuant to each of the Plans, as detailed above, shall collectively be referred to herein as the Awards.

The Plans are designed to reflect the provisions of the Israeli Income Tax Ordinance, or the Ordinance, mainly Sections 102 and 3(i), which affords certain tax advantages to Israeli employees, officers, and directors that are granted options in accordance with its terms. Section 102 of the Ordinance allows employees, directors, and officers, who are not controlling shareholders and who are Israeli residents, to receive favorable tax treatment for compensation in the form of shares, options, restricted shares, restricted share units, and other equity incentive awards. Section 102 of the Ordinance includes two alternatives for tax treatment involving the issuance of equity incentive awards to a trustee for the benefit of the grantees and also includes an additional alternative for issuance directly to the grantee. Sections 102(b)(2) and 102(b)(3) of the Ordinance, which provide the most favorable tax treatment for grantees, permit the issuance to a trustee under the "capital gains track." In order to comply with the terms of the capital gains track, all equity incentive awards granted under a specific plan and subject to the provisions of Section 102 of the Ordinance, as well as the shares issued upon exercise of any such equity incentive awards and other shares received following any realization of rights with respect to such equity incentive awards, such as share dividends and share splits, must be registered in the name of a trustee selected by the board of directors and held in trust for the benefit of the relevant grantee. The trustee may not release such equity incentive awards to the relevant grantee before the second anniversary of the registration of the options in the name of the trustee. However, under this track, our ability to deduct an expense with respect to the issuance of the equity incentive awards might be limited. Section 3(i) of the Ordinance does not provide for similar tax benefits.

The Plans may be administered by our board of directors either directly or upon the recommendation of a committee appointed by our board of directors.

The board of directors determines or approves (and with respect to office holders, following the approval of our compensation committee), the eligible individuals who receive Awards under the Plans, the number of ordinary shares covered by those Awards, the terms under which such Awards may be exercised, and other terms and conditions of the Awards, all in accordance with the provisions of each of the Plans. Award holders may not transfer their Award except in the event of death or transfer to an Administrator in accordance with law in the event of the absence of legal competency. Our compensation committee or board of directors may, at any time, amend or terminate each of the Plans; however, any amendment or termination may not adversely affect any Awards granted under such Plan prior to such action.

The Award exercise price, if any, is determined by the board of directors, and with respect to grants to a director or officer, by the compensation committee prior to the board of directors, and is specified in each Award agreement.

Awards granted under the 2010 Plan and 2024 Plan vest over four years from the vesting commencement date such that 25% vest on the first anniversary of the vesting commencement date and an additional 6.25% vest at the end of each subsequent three-month period thereafter for 36 months, unless otherwise determined by the Plan's administrator.

Under each of the Plans, Awards (other than certain incentive share options), that are not exercised within 10 years from the grant date expire, unless a shorter period is determined by our board of directors or upon an event of termination, as detailed below. Pursuant to an amendment to our 2010 Plan, the term of an option granted under the 2010 Plan may be further extended by an additional five years at the discretion of our board of directors and subject to applicable laws. Except as otherwise determined by the board of directors or as set forth in a grantee's Award agreement, in the event of termination of employment or services for reasons of disability, death, or retirement, the grantee, or in the case of death, his or her legal successor, may exercise options that have vested prior to termination within a period of 12 months from the date of disability, death, or retirement. If we terminate a grantee's employment or service for cause, all of the grantee's options will expire on the date of termination. If a grantee's employment or service is terminated for any other reason, the grantee may exercise his or her vested options within 90 days of the date of termination, but in any case not past their scheduled expiration date.

The Plans provide for certain adjustments upon changes in capitalization, such as share splits, reverse share splits, share dividends (bonus shares), recapitalization, reclassification, rights issuances and dividends, as stipulated in each of the Plans.

With respect to grants that were made under our 2010 Plan prior to October 2017, in the event of (i) a sale of all or substantially all of our assets or (ii) our consolidation or merger in which we are not the ongoing or surviving corporation, then, and unless otherwise determined in the agreement or by the board, we shall be entitled to determine that all of the outstanding unexercised options held by or for the benefit of any grantee shall be assumed or substituted for an appropriate number of options of the successor company, provided that the aggregate amount of the exercise price for such options shall be equal to the aggregate amount of the exercise price of our unexercised options held by each grantee at such time. Additionally, in the event of termination of employment by the Company within twelve (12) months after a Significant Event (as defined below), the option shall remain exercisable (but only to the extent exercisable at termination and not beyond the scheduled expiration date) for a period of three (3) months following the earlier of such termination or notice of termination (unless the Agreement provides otherwise). "Significant Event" shall mean each of the following: a consolidation or merger of the Company with or into another corporation in which the Company is the ongoing or surviving corporation or in which, if the Company is not the ongoing or surviving corporation, the ongoing or surviving corporation (or, if such transaction is effected through a subsidiary, the parent of such ongoing or surviving corporation) assumes the option or substitutes it with an appropriate option in the surviving corporation (or in the parent as aforesaid).

With respect to the grants that were made under our 2010 Plan since October 2017, the above acceleration provision was amended in a manner that the options' vesting is fully accelerated upon the occurrence of a M&A Transaction or Reorganization: (1) "M&A Transaction" shall mean a "merger" as such term or term of similar nature is defined in the Israeli Companies Law of 1999, as well as (i) a sale of 50% or more of the assets of the Company and its subsidiaries taken as a whole, or the sale or disposition (whether by merger or otherwise) of one or more subsidiaries of the Company if more than 50% of the assets of the Company and its subsidiaries taken as a whole are held by such subsidiary or subsidiaries; (ii) a sale of all or more than 50% of the shares of the share capital of the Company whether by a single transaction or a series of related transactions which occur either over a period of 12 months or within the scope of the same acquisition agreement; (iii) an issuance of shares of the Company, whether by a single transaction or a series of related transactions which occur either over a period of 12 months or within the scope of the same acquisition agreement, that results in the offeree holding more than 50% of the share capital of the Company; or (iv) a merger, consolidation or like transaction of the Company with or into another corporation including a reverse triangular merger, but excluding a merger which falls within the definition of Reorganization; and/or (2) "Reorganization" shall mean any re-domestication of the Company, share flip, creation of a holding Company for the Company which will hold all, or 50% or more, of the shares of the Company or any other transaction involving the Company in which our ordinary shares of the Company outstanding immediately prior to such transaction continue to represent, or are converted into or exchanged for shares that represent, immediately following such transaction, at least a majority, by voting power, of the share capital of the surviving, acquiring or resulting corporation and in which there is no material change to the interests held by the shareholders of the Company prior to such transaction and thereafter. The board may also determine that in the occurrence of a Fund-Raising Transaction (as defined below), that all of the outstanding and unexercised options held by or for the benefit of any grantee shall become fully vested. Such determination shall be specifically determined in the grantee's letter of grant. "Fund-Raising Transaction" shall mean the raise by the Company of at least $10 million by way of public offerings and/or private placements of equity securities by one transaction or more, except in the event of issuance of equity securities in connection with the grant in exchange for services or as part of a commercial transaction.

Under our 2024 Plan, in the event of an M&A Transaction, which bears the same definition as in our 2010 Plan, the vesting of the unvested portion of any Award shall be automatically accelerated and such portion shall become fully vested and exercisable, unless determined otherwise by the administrator of the Plan on the date of grant of the Award. Any Award not exercised by the grantee shall be treated in the administrator's sole and absolute discretion, including in one of the following manners: (i) assumption or substitution of the outstanding Awards with equivalent awards or the rights to receive consideration by the acquiring or successor corporation or an affiliate thereof; and/or (ii) the outstanding Awards shall become exercisable in full prior to the date of consummation of the M&A Transaction, or on another date and/or dates or at an event and/or events as the administrator shall determine at its sole and absolute discretion; and/or (iii) that all or a portion or certain categories of the outstanding Awards shall be cancelled upon the actual consummation of the M&A Transaction and instead the holders thereof will receive consideration (by cash including cash-out of the Awards for the net value and/or securities), or no consideration.

Under the 2024 Plan, in the event of a Spin-Off, as defined below, the administrator of the Plan may determine that the holders of Awards shall be entitled to receive equity in the new company formed as a result of the Spin-Off, in accordance with equity granted to our ordinary shareholders within the Spin-Off, taking into account the terms of the Awards, including the vesting schedule and exercise price. The determination regarding grantee's entitlement within the scope of a Spin-Off shall be in the sole and absolute discretion of the administrator. "**Spin-Off**" shall mean any transaction in which assets of the Company or shares of the Company are transferred or sold to a company or corporate entity in which the shareholders of the Company hold the same respective ownership stakes they are then holding in the Company.

F. Disclosure of a registrant's action to recover erroneously awarded compensation.

There was no erroneously awarded compensation that was required to be recovered pursuant to the CollPlant Biotechnologies Ltd. Clawback Policy during the fiscal year ended December 31, 2024.

ITEM 7. MAJOR SHAREHOLDERS AND RELATED PARTY TRANSACTIONS

A. Major Shareholders

The following table sets forth information with respect to the beneficial ownership of our ordinary shares as of March 15, 2025 by:

- each of our directors and senior management;
- all of our directors and senior management as a group; and
- each person (or group of affiliated persons) known by us to be the beneficial owner of 5% or more of the outstanding ordinary shares.

Beneficial ownership is determined in accordance with the rules of the SEC. These rules generally attribute beneficial ownership of securities to persons who possess sole or shared voting or investment power with respect to those securities, and include shares subject to options and warrants that are exercisable within 60 days after March 15, 2025. Such shares are also deemed outstanding for purposes of computing the percentage ownership of the person holding the option, but not the percentage ownership of any other person.

Unless otherwise indicated below, to our knowledge, all persons named in the table have sole voting and investment power with respect to their shares, except to the extent that authority is shared by spouses under community property laws. None of our shareholders has informed us that he, she, or it is affiliated with a registered broker-dealer or is in the business of underwriting securities. None of our shareholders has different voting rights from other shareholders.

	Ordinary Shares Beneficially Owned	Percentage Beneficially Owned**
Senior Management and Directors		
Dr. Roger Pomerantz (1)	200,213	1.7%
Abraham Havron (2)	35,000	*
Dr. Elan Penn (3)	41,000	*
Joseph Zarzewsky (4)	41,000	*
Hugh Evans (5)	416,991	3.6%
Alisa Lask (6)	35,250	*
Yehiel Tal (7)	354,203	3.0%
Eran Rotem (8)	186,707	1.6%
Philippe Bensimon (9)	87,375	*
Hadas Dreiher Horowitz (10)	42,187	*
Elana Gazal (11)	28,125	*
Oren Fahimipoor (12)	25,000	*
All senior management and directors as a group (12 persons)	1,493,051	11.9%
More than 5% Shareholders		
Ami Sagy (13)	1,943,184	17.0%
Loewenbaum Group (14)	1,449,079	12.7%

* Less than 1%

** Based on 11,454,512 ordinary shares outstanding

(1) Consists of (i) options to purchase 162,713 ordinary shares NIS 1.50 par value at an exercise price of $6.39 per share and expiring on February 6, 2030 and (ii) options to purchase 37,500 ordinary shares at an exercise price of $6.39 per share and expiring on May 2, 2032. Does not include options to purchase 12,500 ordinary shares and 50,000 restricted share units, that vest in more than 60 days of March 15, 2025.

(2) Consists of (i) options to purchase 4,000 ordinary shares NIS 1.50 par value at an exercise price of $4.02 per share and expiring on January 14, 2028, (ii) options to purchase 5,000 ordinary shares at an exercise price of $5.07 per share and expiring on January 30, 2026 (iii) options to purchase 8,000 ordinary shares at an exercise price of $6.39 per share and expiring on August 27, 2030. and (iv) options to purchase 18,000 ordinary shares at an exercise price of $6.39 per share and expiring on May 2, 2032. Does not include options to purchase 6,000 ordinary shares and 10,000 restricted share units, that vest in more than 60 days of March 15, 2025.

(3) Consists of (i) options to purchase 10,000 ordinary shares NIS 1.50 par value at an exercise price of $4.02 per share and expiring on January 14, 2028, (ii) options to purchase 5,000 ordinary shares at an exercise price of $5.07 per share and expiring on January 30, 2026 (iii) options to purchase 8,000 ordinary shares at an exercise price of $6.39 per share and expiring on August 27, 2030, and (iv) options to purchase 18,000 ordinary shares at an exercise price of $6.39 per share and expiring on May 2, 2032. Does not include options to purchase 6,000 ordinary shares and 10,000 restricted share units, that vest in more than 60 days of March 15, 2025.

(4) Consists of (i) options to purchase 15,000 ordinary shares NIS 1.50 par value at an exercise price of $4.02 per share and expiring on December 31, 2026 and (ii) options to purchase 8,000 ordinary shares NIS 1.50 par value at an exercise price of $6.39 per share and expiring on August 27, 2030, and (iii) options to purchase 18,000 ordinary shares at an exercise price of $6.39 per share and expiring on May 2, 2032. Does not include options to purchase 6,000 ordinary shares and 10,000 restricted share units, that vest in more than 60 days of March 15, 2025.

(6) Consists of options to purchase 35,250 ordinary shares at an exercise price of $6.39 per share and expiring on May 2, 2032. Does not include options to purchase 11,750 ordinary shares and 10,000 restricted share units, that vest in more than 60 days of March 15, 2025.

(5) Consists of (i) 377,429 ordinary shares and (ii) options to purchase 21,562 ordinary shares NIS 1.50 par value at an exercise price of $6.39 per share and expiring on May 26, 2031, and (iii) options to purchase 18,000 ordinary shares at an exercise price of $6.39 per share and expiring on May 2, 2032. Does not include options to purchase 7,438 ordinary shares and 10,000 restricted share units, that vest in more than 60 days of March 15, 2025.

(7) Consists of (i) 31,137 ordinary shares, (ii) options to purchase 37,800 ordinary shares exercisable at an exercise price of $4.02 per share and expiring on July 31, 2028, (iii) options to purchase 75,000 ordinary shares exercisable at an exercise price of $4.02 per share and expiring on January 14, 2028, (iv) options to purchase 54,000 ordinary shares at an exercise price of $5.07 per share and expiring on January 30, 2026, (v) options to purchase 81,266 ordinary shares at an exercise price of $6.39 per share and expiring on May 26, 2030, and (vi) options to purchase 75,000 ordinary shares at an exercise price of $6.39 per share and expiring on May 2, 2032. Does not include options to purchase 25,000 ordinary shares and 80,000 restricted share units, that vest in more than 60 days of March 15 2025.

(8) Consists of (i) options to purchase 9,000 ordinary shares exercisable at an exercise price of $4.02 per share and expiring on May 18, 2028, (ii) options to purchase 45,000 ordinary shares exercisable at an exercise price of $4.02 per share and expiring on December 26, 2027, (iii) options to purchase 15,000 ordinary shares at an exercise price of $5.07 per share and expiring on January 30, 2026, (iv) options to purchase 52,707 ordinary shares at an exercise price of $6.39 per share and expiring on May 26, 2030, and (v) options to purchase 65,000 ordinary shares at an exercise price of $6.39 per share and expiring on January 27, 2032. Does not include options to purchase 15,000 ordinary shares and 60,000 restricted share units, that vest in more than 60 days of March 15, 2025.

(9) Consists of (i) 2,000 ordinary shares, (ii) options to purchase 9,000 ordinary shares exercisable at an exercise price of $4.02 per share and expiring on May 18, 2028, (iii) options to purchase 15,000 ordinary shares exercisable at an exercise price of $4.02 per share and expiring on December 26, 2027, (iv) options to purchase 16,000 ordinary shares at an exercise price of $5.07 per share and expiring on January 30, 2026, (v) options to purchase 21,000 ordinary shares at an exercise price of $6.39 per share and expiring on May 26, 2030, and (vi) options to purchase 24,375 ordinary shares at an exercise price of $6.39 per share and expiring on January 27, 2032. Does not include options to purchase 5,625 ordinary shares and 30,000 restricted share units, that vest in more than 60 days of March 15, 2025.

(10) Consists of (i) options to purchase 30,000 ordinary shares exercisable at an exercise price of $6.39 per share and expiring on March 25, 2031 and (ii) options to purchase 12,187 ordinary shares at an exercise price of $6.39 per share and expiring on January 27, 2032. Does not include options to purchase 2,813 ordinary shares and 20,000 restricted share units, that vest in more than 60 days of March 15, 2025.

(11) Consists of options to purchase 28,125 ordinary shares exercisable at an exercise price of $5.33 per share and expiring on November 30, 2032. Does not include options to purchase 21,875 ordinary shares and 20,000 restricted share units, that vest in more than 60 days of March 15, 2025.

(12) Consists of options to purchase 25,000 ordinary shares exercisable at an exercise price of $7.5 per share and expiring on March 28, 2033. Does not include options to purchase 25,000 ordinary shares and 30,000 restricted share units, that vest in more than 60 days of March 15, 2025.

(13) Consists of 1,943,184 ordinary shares.

(14) Based on information contained in a Schedule 13G/A filed with the SEC on January 28, 2025 by George Walter Loewenbaum, Lillian S. Loewenbaum, Elizabeth S. Loewenbaum, , Lillian S. Loewenbaum Grantor Retained Annuity Trust I, Lillian S. Loewenbaum Grantor Retained Annuity Trust V, Lillian S. Loewenbaum Grantor Retained Annuity Trust VI, The Loewenbaum 1992 Trust, and The Waterproof Partnership, Ltd. Consists of (i) 1,140,950 ordinary shares underlying shares held by George Walter Loewenbaum, (ii) 89,573 ordinary shares held by Lillian S. Loewenbaum, (iii) 20,688 ordinary shares held by the Elizabeth S. Loewenbaum, (iv) 6,283 ordinary shares held in the Lillian S. Loewenbaum Grantor Retained Annuity Trust I, (v) 10,360 ordinary shares held in the Lillian S. Loewenbaum Grantor Retained Annuity Trust V, (vi) 16,195 ordinary shares held in the Lillian S. Loewenbaum Grantor Retained Annuity Trust VI, (vii) 106,030 ordinary shares held by The Loewenbaum 1992 Trust, (viii) 35,500 ordinary shares held by The Waterproof Partnership, Ltd., (ix) 11,800 ordinary shares held by The Loewenbaum Residence Trust FBO Anna Loewenbaum, and (x) 11,700 ordinary shares held by The Elizabeth Scott Loewenbaum 1992 Trust.

On April 3, 2024, the board of directors (following the approval of the compensation committee with respect to the Company's directors and officers) approved to extend the expiry date of 337,464 options exercisable into 337,464 ordinary shares that were previously granted to some of our employees and directors, from an expiry date ranging between December 2024 and July 2025, by an additional three years, such that the expiry dates will range between December 2027 and July 2028. Out of the said options, 126,800 options exercisable into 126,800 ordinary shares are held by some of the Company's directors and by its CEO (who also serves as a director on the board of directors), and as such, the extension of the expiry dates of these options was subject to the receipt of shareholders' approval by the required majorities under applicable law, which approval was obtained on September 25, 2024 at the Company's general meeting of shareholders.

To our knowledge, other than as disclosed in the table above, our other filings with the SEC and this Annual Report, there has been no significant change in the percentage ownership held by any major shareholder since January 1, 2022.

B. Related Party Transactions

The following is a description of the material terms of those transactions with related parties to which we are party and which were in effect since January 1, 2022. The descriptions provided below are summaries of the terms of such agreements and do not purport to be complete and are qualified in their entirety by the complete agreements.

We believe that we have executed all of our transactions with related parties on terms no less favorable to us than those we could have obtained from unaffiliated third parties. See "Item 6.C. Board Practices—Approval of Related Party Transactions under Israeli Law."

Agreements with Yissum

We have entered into certain agreements with Yissum, in which Prof. Oded Shoseyov, our former Executive Chief Scientist, has or might have a personal interest, including an agreement dated July 13, 2004 with respect to the intellectual property rights relating to our rhCollagen. See "Item 4.B. Business Overview—Intellectual Property—Agreement with Yissum Research Development Company of the Hebrew University of Jerusalem Ltd. with Respect to Our rhCollagen," and see "Item 6.C. Board Practices—Approval of Related Party Transactions Under Israeli Law."

Agreement with Our Subsidiary

The Company has contracted CollPlant Ltd., the Company's wholly owned subsidiary, for its management and administrative services, for which CollPlant Ltd. pays the Company NIS 400,000 on a monthly basis. The parties entered into an investment agreement in November 2024 which includes among others, previous cash investments, on account of share premium, between January 1, 2022, and November 26, 2024. Additionally, in accordance with the agreement and to comply with the Israel Tax Authority's requirements for specific tax benefits, the Company ensured that by December 31, 2024, the total investment in the subsidiary constituted at least 80% of the Company's total assets.

Agreements with Directors and Senior Management

Insurance, Exemption, and Indemnification Agreements

We have entered into indemnification agreements with each of our current directors and executive officers exempting them from a breach of their duty of care to us to the fullest extent permitted by law, subject to limited exceptions, and undertaking to indemnify them to the fullest extent permitted by Israeli law, subject to limited exceptions, and including with respect to liabilities resulting from an offering of securities by us to the extent such liabilities are not covered by insurance. See "Item 6.C. Board Practices—Approval of Related Party Transactions Under Israeli Law—Exemption, Insurance and Indemnification of Directors and Officers."

On July 18, 2023, our shareholders approved, following the approvals of our compensation committee and board of directors, the adoption and grant of a new letter of indemnification for our current and future directors and officers, as may be from time to time, including to our CEO.

The following is a brief summary of the principal changes reflected in the new letter of indemnification.

- Addendum of Events for which Financial Liabilities will be Indemnified – the addendum which stipulates the events for which financial liabilities will be indemnified was updated to reflect the events that our board of directors has determined are likely to occur in light of our operations;

- Indemnification Limits per Event – the per-event indemnification limit stipulated in the addendum to our previous letter of indemnification was removed, such that the indemnification per event shall not be limited other than by the Limit Amount, as defined in the new letter of indemnification, which has remained unchanged;

- Defense of Claim – where we have assumed the defense of the indemnitee in a claim, certain changes have been made with respect to conflicts of interest that may arise, including that the Company will be the person to determine the existence of a conflict of interest, instead of the attorney as was stipulated in our previous letter of indemnification;

- Presumption of Entitlement to Indemnification – the new letter of indemnification clarifies that the presumption is that the indemnitee is entitled to indemnification under the letter of indemnification, and we, the Company, shall have the burden of proof to overcome that presumption;

- Indemnification in the Event of a Counterclaim – the new letter of indemnification stipulates that we will not be required to indemnify or advance any Expenses (as defined in the new letter of indemnification) to the indemnitee with respect to a counter claim made by us or in our name in connection with a claim against us filed by the indemnitee;

- Mechanism for Payment of Indemnification – the mechanism of payment of indemnification amounts has been updated in the new letter of indemnification such that the payment by us for any Expenses (as defined in the new letter of indemnification) will be grossed up to cover any tax payment that the indemnitee may be required to make and will be paid as soon as practicable, and in any event within 15 days from receipt of a written demand;

- Reimbursement of Indemnification – where we have determined, based on advice from our legal counsel, that the indemnitee was not entitled to indemnification payments, the indemnitee will not be required to repay such amounts if the indemnitee disputes the Company's determination, in which case the indemnitee's obligation to repay us shall be postponed until such dispute is resolved by a court of competent jurisdiction in a final and non-appealable order;

- Third Party Indemnification – the new letter of indemnification contains a provision concerning third-party indemnification undertakings, stipulating that where the indemnitee may be entitled to indemnification from other sources, we acknowledge that we are the indemnitor of first resort.

Our board of directors approved that the indemnification undertaking relating to financial liabilities imposed on an indemnitee in favor of another person by any court judgment, including a judgment given as a result of a settlement or an arbitrator's award which has been confirmed by a court, or what we refer to as Financial Liabilities, is limited to the events listed in the letter of indemnification which are foreseeable in light of our activities on the date of its approval, and that the maximum indemnification amount provided in the letter of indemnification is reasonable under the circumstances.

In relation to Financial Liabilities, the maximum indemnification amount that we have undertaken to indemnify our office holders is twenty-five (25%) of our consolidated shareholders' equity as is in accordance with our most recent consolidated annual financial statements, that existed as of the actual date of payment for the indemnification, or what we refer to as the Limit Amount. In the event the indemnification amount that we are required to pay to our office holders exceeds the Limit Amount (as existing at that time), the Limit Amount or its remaining balance will be allocated pro rata between the office holders entitled to indemnification, in the manner that the amount of indemnification that each office holder will actually receive will be calculated in accordance with the ratio between the amount each individual office holder may be indemnified for, and the aggregate amount that all officer holders involved in the event may be indemnified for at the time of the indemnification.

Any existing indemnification or similar agreements with any director or officer that served upon the adoption of our new letter of indemnification was cancelled and replaced by the new letter of indemnification. Notwithstanding the foregoing, the grant of the new letters of indemnification to the current and future directors and officers of the Company does not derogate in any way from any indemnification undertaking we have made in the past, provided however, that the aggregate indemnification amount pursuant to all letters of indemnification granted or that will be granted by us to current and future directors and officers, as well as to current and future employees of the Company who serve as directors or officers in corporations held by the Company (including in their capacity in other roles in the Company or any corporation held by the Company), and including such directors, officers and employees who no longer serve at or are employed by the Company, will not exceed the Limit Amount.

Employment and Services Agreements

We have entered into employment or services agreements with our senior management. See "Item 6.B. Compensation."

Share-based compensation

We have granted share-based compensation to certain of our officers and directors. See "Item 6.B. Compensation" and "Item 7.A. Major Shareholders." We describe our share award plans under "Item 6.E. Share Ownership" and "Item 7.A. Major Shareholders."

C. Interests of Experts and Counsel

Not applicable.

ITEM 8. FINANCIAL INFORMATION.

A. Consolidated Statements and Other Financial Information.

See "Item 18. Financial Statements."

Legal Proceedings

See "Item 4.B. Business Overview—Legal Proceedings."

Dividends

We have never declared or paid cash dividends to our shareholders. Currently, we do not intend to pay cash dividends. We intend to reinvest any earnings in developing and expanding our business. Any future determination relating to our dividend policy will be at the discretion of our board of directors and will depend on a number of factors, including future earnings, our financial condition, operating results, contractual restrictions, capital requirements, business prospects, applicable Israeli law and other factors our board of directors may deem relevant. In addition, the distribution of dividends is limited by Israeli law, which permits the distribution of dividends only out of distributable profits (subject to limited exceptions) and only if there is no reasonable concern that such distribution will prevent us from meeting our existing and future obligations when they become due.

Pursuant to the Companies Law, the distribution amount is limited to the greater of retained earnings or earnings generated over the previous two years, according to our then last reviewed or audited financial statements, provided that the date of the financial statements is not more than six months prior to the date of the distribution, or we may distribute dividends that do not meet such criteria with court approval. In each case, we are only permitted to distribute a dividend if our board of directors and the court, if applicable, determines that there is no reasonable concern that payment of the dividend will prevent us from satisfying our existing and foreseeable obligations as they become due, which is referred to as the Solvency Test. Pursuant to regulations promulgated under the Companies Law, Israeli companies listed on certain non-Israeli stock exchanges, including the Nasdaq, may distribute a dividend by way of a share repurchase program (buy-back) if the company does not meet the profit test, without seeking the approval of the court, subject to the following conditions: (i) the company meets the Solvency Test; and (ii) the company provides a notice to certain creditors of its intention to distribute a dividend by way of a share repurchase program without meeting the profit test and no such creditor submits an objection within 30 days of the notice (otherwise, court approval would be required for such distribution in accordance with the requirements of the Israeli Companies Law).

B. Significant Changes

Other than as otherwise described in this Annual Report on Form 20-F and as set forth below, no significant change has occurred in our operations since the date of our consolidated financial statements included in this Annual Report on Form 20-F.

ITEM 9. THE OFFER AND LISTING

A. Offer and Listing Details

On May 25, 2021, our ordinary shares were approved for trading on the Nasdaq Global Market, and began trading at the open of market on June 4, 2021. At such time, our former securities ADSs were mandatorily cancelled and exchanged for ordinary shares at a one-for-one ratio. Prior to that, our ADSs were quoted on the OTCQX from March 2015 to May 25, 2017, on the OTCQB from May 26, 2017 to January 30, 2018 and on the Nasdaq Capital Market from January 31, 2018 to June 3, 2021 under the symbol “CLGN”. In 2018, we delisted our ordinary shares from trading on the Tel Aviv Stock Exchange, or TASE, and the last date of trading of our ordinary shares on the TASE was on October 29, 2018.

B. Plan of Distribution

Not applicable.

C. Markets

Our ordinary shares are listed on the Nasdaq Global Market.

D. Selling Shareholders

Not applicable.

E. Dilution

Not applicable.

F. Expenses of the Issue

Not applicable.

ITEM 10. ADDITIONAL INFORMATION

A. Share Capital

Not applicable.

B. Memorandum and Articles of Association

Copies of our Memorandum of Association and Amended and Restated Articles of Association are attached as Exhibits 1.1 and 1.2 to this Annual Report, respectively. Other than as disclosed below, the information called for by this Item is set forth in Exhibit 2.1 to this Annual Report and is incorporated by reference into this Annual Report.

C. Material Contracts

We have not entered into any material contract within the two years prior to the date of this Annual Report on Form 20-F, other than contracts entered into in the ordinary course of business, or as otherwise described herein in "Item 4.A. History and Development of the Company", "Item 4.B. Business Overview", "Item 7A. Major Shareholders" or "Item 7B. Related Party Transactions" above.

D. Exchange Controls

There are currently no Israeli currency control restrictions on remittances of dividends on our ordinary shares, proceeds from the sale of the shares or interest or other payments to non-residents of Israel, except for shareholders who are subjects of countries that are, or have been, in a state of war with Israel.

E. Taxation.

The following description is not intended to constitute a complete analysis of all tax consequences relating to the acquisition, ownership and disposition of our ordinary shares. You should consult your own tax advisor concerning the tax consequences of your particular situation, as well as any tax consequences that may arise under the laws of any state, local, foreign, or other taxing jurisdiction.

Israeli Tax Considerations

The following is a brief summary of certain material Israeli tax laws applicable to us, and certain Israeli government programs that benefit us. This section also contains a discussion of certain material Israeli tax consequences concerning the ownership and disposition of our ordinary shares. This summary does not discuss all the aspects of Israeli tax law that may be relevant to a particular investor in light of his or her personal investment circumstances or to some types of investors subject to special treatment under Israeli law. Examples of such investors include residents of Israel or traders in securities who are subject to special tax regimes not covered in this discussion. To the extent that the discussion is based on tax legislation that has not yet been subject to judicial or administrative interpretation, we cannot assure you that the appropriate tax authorities or the courts will accept the views expressed in this discussion. The discussion below is not intended, and should not be construed, as legal or professional tax advice and is not exhaustive of all possible tax considerations. The discussion is subject to change, including due to amendments under Israeli law or changes to the applicable judicial or administrative interpretations of Israeli law, which change could affect the tax consequences described below, possibly with a retroactive effect.

THEREFORE, YOU ARE URGED TO CONSULT YOUR OWN TAX ADVISORS AS TO THE ISRAELI OR OTHER TAX CONSEQUENCES OF THE PURCHASE, OWNERSHIP AND DISPOSITION OF OUR SHARES, INCLUDING, IN PARTICULAR, THE EFFECT OF ANY FOREIGN, STATE OR LOCAL TAXES.

General Corporate Tax Structure in Israel

Israeli Resident Companies, such as us, are generally subject to corporate tax, on their taxable income, at the rate of 23% as of 2018. A corporation will generally be considered as an "Israeli Resident Company" if it meets one of the following: (i) it was incorporated in Israel; or (ii) the control and management of its business are exercised in Israel.

However, the effective tax rate payable by a company that derives income from a Preferred Enterprise or a Preferred Technological Enterprise (as discussed below) may be considerably lower. Capital gains derived by an Israeli company are generally subject to tax at the prevailing corporate tax rate.

Law for the Encouragement of Industry (Taxes), 5729-1969

The Law for the Encouragement of Industry (Taxes), 5729-1969, or the Industry Encouragement Law, provides several tax benefits for "Industrial Companies."

The Industry Encouragement Law defines an "Industrial Company" as a company resident in Israel, of which 90% or more of its income in any tax year, other than income from certain government loans, capital gains, interest and dividends, is derived from an "Industrial Enterprise" owned by it and located in Israel or in the "Area," in accordance with the definition under Section 3A of the Israeli Income Tax Ordinance (New Version) 1961, or the Ordinance. An "Industrial Enterprise" is defined as an enterprise whose principal activity in a given tax year is industrial production.

The following corporate tax benefits, among others, are available to Industrial Companies:

- amortization over an eight-year period, commencing on the year in which such rights were first exercised, of the cost of patents and rights to use a patent and know-how which were purchased in good faith and are used for the development or advancement of the Industrial Enterprise;
- deduction over a three-year period of expenses incurred in connection with the issuance and listing of shares on a stock market; and
- under certain conditions, an election to file consolidated tax returns with related Israeli Industrial Companies.

There can be no assurance that we currently qualify, or will continue to qualify, as an Industrial Company or that the benefits described above will be available in the future.

Law for the Encouragement of Capital Investments, 5719-1959

Tax Benefits for Income from Preferred Enterprise

The Law for the Encouragement of Capital Investments, 5719-1959, or the Investment Law, currently provides certain tax benefits for income generated by a "Preferred Company" through its "Preferred Enterprise". The definition of a Preferred Company includes, *inter alia,* a company incorporated in Israel that is not wholly owned by a governmental entity, which:

- owns a Preferred Enterprise, which is defined as an "Industrial Enterprise" (as defined under the Investment Law) that is classified as either a "Competitive Enterprise" (as defined under the Investment Law) or a "Competitive Enterprise in the Field of Renewable Energy" (as defined under the Investment Law);
- is controlled and managed from Israel;
- is not a "Family Company," a "Transparent Company," or a "Kibbutz" (collective community) as defined under the Ordinance;
- keeps acceptable books of account and files reports in accordance with the provisions of the Investment Law and the Ordinance; and
- was not, and certain officers of which were not, convicted of certain crimes in the 10 years prior to the tax year with respect to which benefits are being claimed.

As of January 1, 2017, a Preferred Company is currently entitled to a reduced corporate tax rate of 16% with respect to its income derived by its Preferred Enterprise, unless the Preferred Enterprise is located in development area A, in which case the rate is currently 7.5% (our operations are currently not located in development area A).

Dividends distributed from income generated from a Preferred Enterprise are subject to tax at the rate of 20% or to a lower rate as may be provided in an applicable tax treaty. However, if such dividends are distributed to an Israeli company, such dividends are exempt from tax (unless such dividends are subsequently distributed to individuals or a non-Israeli company).

If in the future we generate taxable income, to the extent that we qualify as a "Preferred Company," the benefits provided under the Investment Law could potentially reduce our corporate tax liabilities. Therefore, the termination or substantial reduction of the benefits available under the Investment Law could materially increase our tax liabilities.

Tax Benefits for Income from Preferred Technological Enterprise

An amendment to the Investment Law was enacted as part of the Economic Efficiency Law that was published on December 29, 2016, and became effective as of January 1, 2017, or the 2017 Amendment. The 2017 Amendment provides new tax benefits for two types of "Technological Enterprises," as described below, and is in addition to the other existing tax beneficial programs under the Investment Law.

The 2017 Amendment provides that a Preferred Company satisfying certain conditions will qualify as having a "Preferred Technological Enterprise" and will thereby enjoy a reduced corporate tax rate of 12% on income that qualifies as "Preferred Technological Income," as defined in the Investment Law. The corporate tax rate is further reduced to 7.5% with respect to a Preferred Technological Enterprise located in development area A. In addition, a Preferred Company qualify as having a "Preferred Technological Enterprise" will enjoy a reduced corporate tax rate of 12% on capital gain derived from the sale of certain "Benefitted Intangible Assets" (as defined in the Investment Law) to a related foreign company if the Benefitted Intangible Assets were acquired from a foreign company on or after January 1, 2017 for at least NIS 200 million, and the sale receives prior approval from the IIA.

The 2017 Amendment further provides that a "Preferred Company" satisfying certain conditions (including group consolidated revenues of at least NIS 10 billion) will qualify as having a "Special Preferred Technological Enterprise" and will thereby enjoy a reduced corporate tax rate of 6% on "Preferred Technological Income" regardless of the company's geographic location within Israel. In addition, a "Special Preferred Technological Enterprise" will enjoy a reduced corporate tax rate of 6% on capital gain derived from the sale of certain "Benefitted Intangible Assets" to a related foreign company if the "Benefitted Intangible Assets" were either developed by the "Special Preferred Enterprise" or acquired from a foreign company on or after January 1, 2017, and the sale received prior approval from the IIA. A "Special Preferred Technological Enterprise" that acquires "Benefitted Intangible Assets" from a foreign company for more than NIS 500 million will be eligible for these benefits for at least ten years, subject to certain approvals as specified in the Investment Law.

Dividends distributed by a Preferred Technological Enterprise that are paid out of Preferred Technological Income are subject to tax at the rate of 20%, but if such dividends are distributed to a foreign company and at least 90% of the shares of the distributing company are held by foreign resident companies then the tax rate may be as low as 4%, subject to the fulfillment of certain conditions.

As we have not yet generated taxable income, there is no assurance that we qualify as a Preferred Technological Enterprise or that the benefits described above will be available to us in the future.

If in the future we generate taxable income, to the extent that we qualify as a "Preferred Company", the benefits provided under the Investment Law could potentially reduce our corporate tax liabilities. Therefore, the termination or substantial reduction of the benefits available under the Investment Law could materially increase our tax liabilities.

The Encouragement of Research, Development and Technological Innovation in the Industry Law 5744

Under the Encouragement of Research, Development and Technological Innovation in the Industry Law 5744-1984 (formerly known as the Law for the Encouragement of Research and Development in Industry 5744-1984), or Innovation Law, and the regulations and guidelines promulgated thereunder, research and development programs which meet specified criteria and are approved by a committee of the IIA, are eligible for grants. The grants awarded are based on certain of the project's expenditures, as determined by the research committee. The grantee is required to pay royalties to the State of Israel from the revenues derived from products developed program the sale of products incorporating technology developed within the framework of the approved research and development program or derived from such program (including ancillary services in connection with such program), linked to the dollar and bearing interest at the LIBOR rate. The terms of the IIA participation also require that products developed with IIA grants be manufactured in Israel and that the know-how developed thereunder may not be transferred outside of Israel, unless approval is received from the IIA and additional payments are made to the IIA. However, this does not restrict the export of products that incorporate the funded know-how. The royalty repayment ceiling can reach up to three times the amount of the grant received (plus interest) if manufacturing is transferred outside of Israel, and repayment of up to six times the amount of the grant (plus interest) may be required if the technology itself is transferred outside of Israel.

Taxation of our Shareholders

Capital Gains Tax

Israeli law generally imposes a capital gains tax (i) on the sale of any capital assets by residents of Israel, as defined for Israeli tax purposes, and (ii) on the sale of capital assets located in Israel, including shares of Israeli companies, by non-residents of Israel, unless a specific exemption is available or unless a tax treaty between Israel and the shareholder's country of residence provides otherwise. The law distinguishes between real gain and inflationary surplus. The inflationary surplus is a portion of the total capital gain that is equivalent to the increase of the relevant asset's purchase price which is attributable to the increase in the Israeli consumer price index, or in certain circumstances a foreign currency exchange rate, between the date of purchase and the date of sale. The real gain is the excess of the total capital gain over the inflationary surplus.

Israeli Residents

Generally, as of January 1, 2012 and thereafter, the tax rate applicable to real capital gains derived from the sale of shares, whether listed on a stock market or not, is 25% for Israeli individuals. Additionally, if such shareholder is considered a "substantial shareholder" at the time of the sale or at any time during the 12-month period preceding such sale, the tax rate will be 30%. A "substantial shareholder" is defined as one who holds, directly or indirectly, alone or "together with another" (i.e., together with a relative, or together with someone who is not a relative but with whom, according to an agreement, there is regular cooperation in material matters of the company, directly or indirectly), holds, directly or indirectly, at least 10% of any of the "means of control" in the company. "Means of control" generally include the right to vote, receive profits, nominate a director or an executive officer, receive assets upon liquidation, or instruct someone who holds any of the aforementioned rights regarding the manner in which such rights are to be exercised. However, different tax rates will apply to dealers in securities. Israeli companies are subject to capital gains tax at the regular corporate tax rate (i.e., 23% for the tax year 2025) on real capital gains derived from the sale of listed shares.

In some instances where our shareholders are liable for Israeli tax on the sale of their ordinary shares, the payment of the consideration may be subject to the withholding at source of Israeli tax at source.

Non-Israeli Residents

A non-Israeli resident who derives capital gains from the sale of shares in an Israeli resident company that were purchased after the company was listed for trading on a stock exchange in Israel (and also if the company was not listed on stock exchange in Israel, under certain conditions) will be exempt from Israeli tax so long as the shares were not held through a permanent establishment that the non-resident maintains in Israel. However, non-Israeli resident corporations will not be entitled to the foregoing exemption if (i) an Israeli resident has a controlling interest, directly or indirectly, alone, "together with another" (as defined above), or together with another Israeli resident, of more than 25% in one or more of the "means of control" (as defined above) in such non-Israeli resident corporation, or (ii) Israeli residents are the beneficiaries of, or are entitled to, 25% or more of the revenues or profits of such non-Israeli resident corporation, whether directly or indirectly. In addition, such exemption is not applicable to a person whose gains from selling or otherwise disposing of the securities are deemed to be business income.

In addition, a sale of securities by a non-Israeli resident may be exempt from Israeli capital gains tax under the provisions of an applicable tax treaty. For example, pursuant to the provisions of the Convention between the Government of the United States of America and the Government of the State of Israel with respect to Taxes on Income, as amended, or the U.S.-Israel Tax Treaty, capital gains arising from the sale, exchange or disposition of our ordinary shares by (i) a person who qualifies as a resident of the United States within the meaning of the U.S.-Israel Tax Treaty, (ii) who holds the shares as a capital asset, and (iii) who is entitled to claim the benefits afforded to such person by the U.S.-Israel Tax Treaty is generally exempt from Israeli capital gains tax. Such exemption will not apply if: (i) such person holds, directly or indirectly, shares representing 10% or more of our voting power during any part of the 12-month period preceding such sale, exchange, or disposition, subject to particular conditions; (ii) the capital gains from such sale, exchange, or disposition are attributable to a permanent establishment in Israel; or (iii) such person is an individual and was present in Israel for 183 days or more during the relevant tax year. In such case, the capital gain arising from the sale, exchange, or disposition of our ordinary shares would be subject to Israeli tax, to the extent applicable; however, under the U.S.-Israel Tax Treaty, the taxpayer may be permitted to claim a credit for such taxes against the U.S. federal income tax imposed with respect to such sale, exchange, or disposition, subject to the limitations under U.S. law applicable to foreign tax credits. The U.S.-Israel Tax Treaty does not relate to U.S. state or local taxes.

Shareholders may be required to demonstrate that they are exempt from tax on their capital gains in order to avoid withholding tax at source at the time of sale.

It should be noted that if the real capital gain realized by an individual shareholder is not exempt from tax in Israel, the tax rates applicable to Israeli resident individual shareholders should generally apply.

In some instances where our shareholders may be liable for Israeli tax on the sale of their ordinary shares, the payment of the consideration may be subject to the withholding of Israeli tax at source.

Taxation of Dividend Distributions

Israeli Residents

Israeli resident individuals are generally subject to Israeli income tax on the receipt of dividends paid in respect to ordinary shares, other than bonus shares (share dividends). As of January 1, 2012 and thereafter, the tax rate applicable to such dividends is generally 25%. With respect to a person who is a "substantial shareholder" (as defined above) at the time the dividend is received or at any time during the preceding 12-month period, the applicable tax rate is 30%. Dividends distributed from income derived from Preferred Enterprises and Preferred Technology Enterprises will generally be subject to income tax at a rate of 20%.

Dividends paid to an Israeli resident individual shareholder on our ordinary shares will generally be subject to withholding tax at the rates corresponding with the income tax rates detailed above unless we are provided in advance with a withholding tax certificate issued by the Israel Tax Authority stipulating a different rate.

Notwithstanding the above, dividends distributed to an Israeli resident "substantial shareholder" (as defined above) on publicly traded shares, like our ordinary shares, which are held via a "nominee company" (as defined under the Israeli Securities Law), are generally subject to Israeli withholding tax at a rate of 25%, unless a different rate is provided under an applicable tax treaty, provided that a certificate from the Israel Tax Authority allowing for a reduced withholding tax rate is obtained in advance.

If the dividend is attributable partly to income derived from a Preferred Enterprise or a Preferred Technology Enterprise and partly to other sources of income, the tax rate will be a blended tax rate reflecting the relative portions of the various types of income. We cannot assure you that we will designate the profits that are being distributed in a way that will reduce shareholders' tax liability.

Israeli resident companies are generally exempt from tax on the receipt of dividends paid on our ordinary shares.

Non-Israeli Residents

Unless relief is provided in a treaty between Israel and the shareholder's country of residence, non-Israeli residents are generally subject to Israeli income tax on the receipt of dividends paid on our ordinary shares at the rate of 25%. With respect to a person (including a corporation) who is a "substantial shareholder" (as defined above) at the time of receiving the dividend or at any time during the preceding 12-month period, absent treaty relief as mentioned above, the applicable capital gains tax rate is 30%. Notwithstanding the above, dividends distributed from income derived from Preferred Enterprises or Preferred Technological Enterprise will be subject to beneficial rates of Israeli tax (as detailed above and subject to the fulfillment of certain conditions).

In this regard, dividends paid to a non-Israeli resident shareholder on our ordinary shares will generally be subject to withholding tax at the rates corresponding with the income tax rates detailed above unless we are provided in advance with a withholding tax certificate issued by the Israel Tax Authority stipulating a different rate (e.g., in accordance with the provisions of an applicable tax treaty).

Notwithstanding the above, dividends paid to a non-Israeli resident "substantial shareholder" (as defined above) on publicly traded shares, like our ordinary shares, which are held via a "nominee company" (as defined under the Israeli Securities Law), are generally subject to Israeli withholding tax at a rate of 25%, unless a different rate is provided under an applicable tax treaty, provided that a certificate from the Israel Tax Authority allowing for a reduced withholding tax rate is obtained in advance.

In addition, it should be noted that an additional 3% tax might be applicable to individual shareholders if certain conditions are met.

Under the U.S.-Israel Tax Treaty, the maximum Israeli tax on dividends paid to a holder of ordinary shares who qualifies as a resident of the United States within the meaning of the U.S.-Israel Tax Treaty is 25%. Such tax rate is generally reduced to 12.5% if: (i) the shareholder is a U.S. corporation and holds at least 10% of the outstanding shares of our voting stock during the part of our tax year that precedes the date of payment of the dividends and during the whole of our prior tax year; (ii) not more than 25% of our gross income in the tax year preceding the payment of the dividends consists of interest or dividends, other than dividends or interest received from subsidiary corporations that 50% or more of the outstanding shares of voting stock of such corporations are owned by us at the time such dividends or interest are received by us; and (iii) the dividends are not sourced from income derived during a period for which we were entitled to the reduced tax rate applicable to a Preferred Enterprise under the Investment Law. If the dividends are sourced from income derived during a period for which we are entitled to the reduced tax rate applicable to a Preferred Enterprise or a Preferred Technological Enterprise under the Investment Law, to the extent that the first two conditions detailed above are met, the Israeli tax rate applicable to such dividends should be 15%.

If the dividend is attributable partly to income derived from a Preferred Enterprise or a Preferred Technological Enterprise and partly to other sources of income, the tax rate will be a blended rate reflecting the relative portions of the various types of income. We cannot assure you that we will designate the profits that are being distributed in a way that will reduce shareholders' tax liability.

Excess Tax

Individuals who are subject to tax in Israel are also subject to an additional tax at a rate of 3% on annual income including, but not limited to, income derived from, dividends, interest and capital gains, exceeding a certain threshold (currently NIS 721,560 for years 2024 through 2027, amount which will be updated annually starting January 1, 2028, based on the change in the Israeli consumer price index) (the "Threshold Amount"). An additional 2% tax applies to "capital income" earned as of January 1, 2025 (including capital gains, dividends, and interest) exceeding the Threshold Amount.

Estate and gift tax

Israeli law presently does not impose estate tax.

Israeli law also does not presently impose gift taxes upon the transfer of assets to Israeli resident individuals so long as it is demonstrated to the satisfaction of the Israel Tax Authority that the transfer was executed in good faith.

Certain Material U.S. Federal Income Tax Consequences

The following summary describes certain material U.S. federal income tax consequences relating to an investment in our ordinary shares. This summary deals only with ordinary shares that are held as capital assets (generally, property held for investment) within the meaning of Section 1221 of the U.S. Internal Revenue Code of 1986, as amended, or the Code, and does not address tax considerations of holders that may be subject to special tax rules, including, but not limited to, dealers or traders in securities or currencies, financial institutions, tax-exempt organizations, insurance companies, regulated investment companies, real estate investment trusts, grantor trusts, individual retirement and tax-deferred accounts, certain former citizens or residents of the United States, persons who acquire our ordinary shares through the exercise or cancellation of employee stock options or otherwise as compensation for their services, persons holding ordinary shares as part of a hedging, integrated, conversion or constructive sale transaction, or a straddle, persons that mark their securities to market for U.S. federal income tax purposes, persons subject to the alternative minimum tax, or persons who have a functional currency other than the U.S. dollar. In addition, this discussion does not address the tax treatment of U.S. holders (as defined below) who own, directly, indirectly, or constructively, 10% or more of our outstanding stock, by vote or value. The summary set forth below relating to U.S. holders is applicable only to such U.S. holders (i) who are residents of the United States for purposes of the U.S.-Israel Tax Treaty, (ii) whose ordinary shares are not, for purposes of the U.S.-Israel Tax Treaty, effectively connected with or attributable to a permanent establishment in Israel, and (iii) who otherwise qualify for the full benefits of the U.S.-Israel Tax Treaty. The discussion below is based upon the Code, final, temporary and proposed Treasury regulations promulgated thereunder, applicable administrative rulings and judicial interpretations thereof, and the U.S.-Israel Tax Treaty, all as in effect as of the date of this Annual Report on Form 20-F and all of which are subject to change, possibly on a retroactive basis, and all of which are open to differing interpretations. In addition, this summary does not consider the possible application of U.S. federal gift or estate taxes or any aspect of state, local, or non-U.S. tax laws. Furthermore, we will not seek a ruling from the IRS with regard to the U.S. federal income tax treatment of an investment in our ordinary shares and can provide no assurance that the tax consequences contained in this summary will not be challenged by the IRS or will be sustained in a court if challenged.

As used in this summary the term "U.S. holder" means a beneficial owner of ordinary shares that is, for U.S. federal income tax purposes: (i) an individual citizen or resident of the United States, (ii) a corporation (or other entity taxable as a corporation for U.S. federal income tax purposes) created or organized in or under the laws of the United States or any state thereof, or the District of Columbia; (iii) an estate the income of which is subject to U.S. federal income taxation regardless of its source, or (iv) a trust if either (a) a court within the United States is able to exercise primary supervision over the administration of the trust and one or more U.S. persons have the authority to control all substantial decisions of the trust, or (b) the trust has a valid election in effect under applicable Treasury regulations to be treated as a U.S. person. Except to the limited extent discussed below, this summary does not consider the U.S. federal tax considerations to a person that is not a U.S. holder (a "non-U.S. holder"). In addition, the tax treatment of persons who hold ordinary shares through a partnership or other pass-through entity treated as a partnership for U.S. federal income tax purposes generally depends upon the status of the partner (or person or entity treated as a partner) and the activities of the partnership. The tax consequences to such a partner or partnership are not considered in this summary and partners and partnerships should consult their tax advisors with respect to the U.S. federal tax consequences of investing in our ordinary shares.

This summary does not discuss all aspects of U.S. federal income taxation that may be relevant to a particular investor in light of its circumstances. Purchasers of our ordinary shares should consult their own tax advisors with respect to the specific U.S. federal income tax consequences to such person of purchasing, holding, or disposing of our ordinary shares, as well as the effect of any state, local, or other tax laws.

Distributions on Ordinary Shares

As noted above, we currently do not expect to pay cash dividends on our ordinary shares in the foreseeable future. Subject to the discussion under the heading "Passive Foreign Investment Company Consequences," U.S. holders are required to include in gross income the amount of any distribution paid on ordinary shares to the extent the distribution is paid out of our current and/or accumulated earnings and profits, as determined for U.S. federal income tax purposes. To the extent a distribution paid with respect to our ordinary shares exceeds our current and accumulated earnings and profits, such amount will be treated first as a non-taxable return of capital, reducing a U.S. holder's tax basis for our ordinary shares to the extent thereof, and thereafter as either long-term or short-term capital gain depending upon whether the U.S. holder has held our ordinary shares for more than one year as of the time such distribution is received. Preferential tax rates for long-term capital gains are applicable for U.S. holders that are individuals, estates, or trusts. However, we do not expect to maintain calculations of our earnings and profits under United States federal income tax principles. Therefore, U.S. holders should expect that the entire amount of any distribution (without reduction for any Israeli tax withheld from such distribution) generally will be reported as dividend income when actually or constructively received. The amount of the dividend will generally be treated as foreign-source dividend income to U.S. holders. A non-corporate U.S. holder that meets certain eligibility requirements may qualify for a lower rate of U.S. federal income taxation on dividends paid if we are a "qualified foreign corporation" for U.S. federal income tax purposes. We generally will be treated as a qualified foreign corporation if we are not a passive foreign investment company, or PFIC, in the taxable year in which such dividends are paid or in the preceding taxable year (see discussion below), and (i) we are eligible for benefits under the United States-Israel income tax treaty or (ii) our ordinary shares are listed on an established securities market in the United States (which includes the Nasdaq Global Market). In addition, a non-corporate U.S. holder will not be eligible for a reduced U.S. federal income tax rate with respect to dividend distributions on ordinary shares if (a) such U.S. holder has not held our ordinary shares for at least 61 days during the 121-day period starting on the date which is 60 days before, and ending 60 days after the ex-dividend date, (b) to the extent the U.S. holder is under an obligation to make related payments on substantially similar or related property, or (c) with respect to any portion of a dividend that is taken into account by the U.S. holder as investment income under Section 163(d)(4)(B) of the Code. Any days during which the U.S. holder has diminished its risk of loss with respect to ordinary shares (for example, by holding an option to sell our ordinary shares) are not counted towards meeting the 61-day holding period. Non-corporate U.S. holders should consult their own tax advisors concerning whether dividends received by them qualify for the reduced rate of tax.

Corporate U.S. holders generally will not be allowed a deduction for dividends received from us.

The amount of a distribution with respect to our ordinary shares equals the amount of cash and the fair market value of any property distributed plus the amount of any Israeli taxes withheld therefrom. The amount of any cash distributions paid in NIS equals the U.S. dollar value of the NIS on the date of distribution based upon the exchange rate in effect on such date, regardless of whether the NIS are converted into U.S. dollars at that time, and U.S. holders who include such distribution in income on such date will have a tax basis in such NIS for U.S. federal income tax purposes equal to such U.S. dollar value. If the dividend is converted to U.S. dollars on the date of receipt, a U.S. holder generally will not recognize a foreign currency gain or loss. However, if the U.S. holder converts the NIS into U.S. dollars on a later date, the U.S. holder must include, in computing its income, any gain or loss resulting from any exchange rate fluctuations. The gain or loss will be equal to the difference between (i) the U.S. dollar value of the amount included in income when the dividend was received and (ii) the amount received on the conversion of the NIS into U.S. dollars. Such gain or loss will generally be ordinary income or loss and United States source income for U.S. foreign tax credit purposes. U.S. holders should consult their own tax advisors regarding the tax consequences to them if we pay dividends in NIS or any other non-U.S. currency.

Subject to certain significant conditions and limitations, including potential limitations under the U.S.-Israel Tax Treaty, U.S. holders may be entitled to a credit against their U.S. federal income tax liability or a deduction against U.S. federal taxable income in an amount equal to the non-refundable Israeli tax withheld on distributions on our ordinary shares. However, as a result of recent changes to the U.S. foreign tax credit rules, a withholding tax may need to satisfy certain additional requirements in order to be considered a creditable tax for a U.S. holder. We have not determined whether these requirements have been met and, accordingly, no assurance can be given that any withholding tax on dividends paid by us will be creditable. The election to deduct, rather than credit, foreign taxes, is made on a year-by-year basis and applies to all foreign taxes paid by a U.S. holder or withheld from a U.S. holder that year. Distributions paid on our ordinary shares will generally be treated as passive income that is foreign source for U.S. foreign tax credit purposes, which may be relevant in calculating a U.S. holder's foreign tax credit limitation. The rules relating to the determination of the foreign tax credit are complex, and U.S. holders should consult their own tax advisors to determine whether and to what extent they would be entitled to such credit.

Disposition of Ordinary Shares

Subject to the discussion under the heading "Passive Foreign Investment Company Consequences," upon the sale, exchange or other disposition of ordinary shares, a U.S. holder generally will recognize capital gain or loss in an amount equal to the difference between the amount realized on the disposition and such U.S. holder's adjusted tax basis in our ordinary shares. The adjusted tax basis in an ordinary share generally will be equal to the cost of such ordinary share. The capital gain or loss realized on the sale, exchange, or other disposition of ordinary shares will be long-term capital gain or loss if the U.S. holder held our ordinary shares for more than one year as of the time of disposition. Preferential tax rates for long-term capital gain will generally apply to non-corporate U.S. holders. Any gain or loss realized by a U.S. holder on the sale, exchange, or other disposition of ordinary shares generally will be treated as from sources within the United States for U.S. foreign tax credit purposes. The deductibility of capital losses for U.S. federal income tax purposes is subject to limitations.

U.S. holders should consult their own tax advisors regarding the U.S. federal income tax consequences of receiving currency other than U.S. dollars upon the disposition of their ordinary shares.

Disclosure of Reportable Transactions

If a U.S. holder sells or disposes of our ordinary shares at a loss or otherwise incurs certain losses that meet certain thresholds, such U.S. holder may be required to file a disclosure statement with the IRS. Failure to comply with these and other reporting requirements could result in the imposition of significant penalties.

Passive Foreign Investment Company Consequences

Generally, a non-U.S. corporation will be a PFIC for U.S. federal income tax purposes in any taxable year in which either (i) 75% or more of its gross income for such year consists of certain types of "passive" income or (ii) 50% or more of the average fair market value of its assets during such year (based on quarterly valuations) produce or are held for the production of passive income. Passive income for this purpose generally includes dividends, interest, rents, royalties, annuities, income from certain commodities transactions and from notional principal contracts, and the excess of gains over losses from the disposition of assets that produce passive income. Passive income also includes amounts derived by reason of the temporary investment of funds, including those raised in a public offering. Assets that produce or are held for the production of passive income may include cash, even if held as working capital or raised in a public offering, as well as marketable securities, and other assets that may produce passive income. In determining whether a non-U.S. corporation is a PFIC, a proportionate share of the income and assets of each corporation in which it owns, directly or indirectly, at least a 25% interest (by value) is taken into account.

A foreign corporation's PFIC status is an annual determination that is based on tests that are factual in nature, and our PFIC status for any year will depend on the composition of our income, fair market value of our assets, and our activities for such year. Based on our non-passive revenue-producing operations for the year ended December 31, 2024, we do not expect to be a PFIC for our 2024 taxable year. Because the PFIC determination is highly fact intensive, there can be no assurance that we were not a PFIC in 2024 and will not be a PFIC in 2025 or any other year. Even if we determine that we are not a PFIC after the close of a taxable year, there can be no assurance that the IRS or a court will agree with our conclusion.

If we were a PFIC for any taxable year during which a U.S. holder held ordinary shares, then unless an election has been made by a U.S. holder to be taxed under one of the alternative regimes discussed below, gain recognized by a U.S. holder on a sale or other disposition (including certain pledges) of our ordinary shares would be allocated ratably over the U.S. holder's holding period for our ordinary shares. The amounts allocated to the taxable year of the sale or other disposition and to any year before we became a PFIC would be taxed as ordinary income. The amount allocated to each other taxable year would be subject to tax at the highest rate in effect for individuals or corporations, as appropriate, for that taxable year, and an interest charge would be imposed on the amount allocated to that taxable year. Similar rules would apply to any distribution with respect to our ordinary shares in excess of 125% of the average of the annual distributions received by a U.S. holder during the preceding three years or such U.S. holder's holding period, whichever is shorter. In addition, non-corporate U.S. holders will not be eligible for reduced rates of taxation on any dividends received from us if we are a PFIC in the taxable year in which such dividends are paid or in the preceding taxable year.

If we are a PFIC for any taxable year during which you hold our ordinary shares and our non-United States subsidiary is also a PFIC (the non-United States subsidiary in such a case, the "lower-tier PFIC"), a U.S. holder would be treated as owning a proportionate amount (by value) of the shares of the lower-tier PFIC for purposes of the application of these rules and a disposition by us of the shares of the lower-tier PFIC or receipt by us of a distribution from the lower-tier PFIC generally will be treated as a deemed disposition of such shares or the deemed receipt of such distribution by the U.S. holder, subject to taxation under the PFIC rules even though the U.S. holder does not receive any proceeds from those dispositions or distributions. There can be no assurance that a U.S. holder will be able to make a "QEF" election with respect to the lower-tier PFIC. U.S. holders are urged to consult their tax advisors about the application of the PFIC rules to our non-United States subsidiary.

If we are treated as a PFIC for any taxable year during the holding period of a non-electing U.S. holder (i.e., a U.S. holder that does not elect to be taxed under one of the alternative regimes discussed below), we will continue to be treated as a PFIC for all succeeding years during which such non-electing U.S. holder is treated as a direct or indirect holder even if we are not a PFIC for such years. A U.S. holder is encouraged to consult its tax advisor with respect to any available elections that may be applicable in such a situation, including the "deemed sale" election of Section 1298(b)(1) of the Code.

Notwithstanding the default PFIC rules described in the preceding paragraphs, certain elections may be available that would result in alternative tax consequences; i.e., the "qualified electing fund" or "QEF" election and the "mark to market" election. If a U.S. holder makes a timely and valid mark-to-market election, the U.S. holder generally will recognize as ordinary income any excess of the fair market value of our ordinary shares at the end of each taxable year over their adjusted tax basis, and will recognize an ordinary loss in respect of any excess of the adjusted tax basis of our ordinary shares over their fair market value at the end of the taxable year (but only to the extent of the net amount of income previously included as a result of the mark-to-market election). The U.S. holder's tax basis in our ordinary shares will be adjusted to reflect the income or loss resulting from the mark-to-market election. Any gain recognized on the sale or other disposition of ordinary shares in a year when we are a PFIC will be treated as ordinary income and any loss will be treated as an ordinary loss (but only to the extent of the net amount of income previously included as a result of the mark-to-market election and any loss in excess of such amount will be treated as capital loss). The mark-to-market election is available only if we are a PFIC and our ordinary shares are "regularly traded" on a "qualified exchange" within the meaning of applicable U.S. Treasury regulations. Our ordinary shares will be treated as "regularly traded" in any calendar year in which more than a de minimis quantity of our ordinary shares are traded on a qualified exchange on at least 15 days during each calendar quarter. Although the IRS has not published any authority identifying specific exchanges that may constitute "qualified exchanges," Treasury Regulations provide that a qualified exchange is (i) a U.S. securities exchange that is registered with the Securities and Exchange Commission, (ii) the U.S. market system established pursuant to Section 11A of the Securities and Exchange Act of 1934, or (iii) a non-U.S. securities exchange that is regulated or supervised by a governmental authority of the country in which the market is located, provided that: (a) such non-U.S. exchange has trading volume, listing, financial disclosure, surveillance, and other requirements designed to prevent fraudulent and manipulative acts and practices, to remove impediments to and perfect the mechanism of a free and open, fair and orderly, market, and to protect investors, and the laws of the country in which such non-U.S. exchange is located and the rules of such non-U.S. exchange ensure that such requirements are actually enforced; and (b) the rules of such non-U.S. exchange effectively promote active trading of listed shares. The Nasdaq Global Market is a qualified exchange for this purpose, but there can be no assurance that the trading in our ordinary shares will be sufficiently regular to qualify our ordinary shares as marketable stock. A mark-to-market election will not apply to ordinary shares held by a U.S. holder for any taxable year during which we are not a PFIC, but will remain in effect with respect to any subsequent taxable year in which we become a PFIC unless our ordinary shares are no longer regularly traded on a qualified exchange or the IRS consents to the revocation of the election. Such election will not apply to any PFIC subsidiary that we own. Each U.S. holder is encouraged to consult its own tax advisor with respect to the availability and tax consequences of a mark-to-market election with respect to our ordinary shares.

Another way in which certain of the adverse consequences of PFIC status can be mitigated is for a U.S. holder to make a QEF election. Generally, a shareholder making the QEF election is required for each taxable year to include in income a pro rata share of our ordinary earnings and net capital gain of the QEF, subject to a separate election to defer payment of taxes, which deferral is subject to an interest charge. An election to treat us as a QEF will not be available if we do not provide the information necessary to make such an election. We are not obligated and do not currently intend to provide the information necessary to make a QEF election and thus it is not expected that a QEF election will be available for U.S. holders of our ordinary shares if we were a PFIC in any prior year, the current year or any future year.

U.S. holders should consult their tax advisors to determine under what circumstances these elections would be available and, if available, what the consequences of the alternative treatments would be in their particular circumstances.

If a U.S. holder holds ordinary shares in any year in which we are treated as a PFIC, the U.S. holder will be required to file IRS Form 8621 and may be subject to certain other information reporting requirements.

The U.S. federal income tax rules relating to PFICs are complex. U.S. holders are urged to consult their own tax advisors with respect to the consequences to them of an investment in a PFIC, any elections available with respect to our ordinary shares and the IRS information reporting obligations with respect to the purchase, ownership, and disposition of our ordinary shares in the event we are determined to be a PFIC.

Medicare Tax on Investment Income

In addition to the income taxes described above, U.S. holders that are individuals, estates, or trusts and whose income exceeds certain thresholds will be subject to a 3.8% tax on all or a portion of their "net investment income," which generally would include dividends on, and dispositions of, our ordinary shares. U.S. holders should consult their tax advisors with respect to the applicability of the 3.8% Medicare tax to their income and gains, if any, resulting from their investment in our ordinary shares.

Information Reporting and Backup Withholding

A U.S. holder may be subject to backup withholding and information reporting requirements with respect to cash distributions and proceeds from a disposition of ordinary shares. In general, backup withholding will apply only if a U.S. holder fails to comply with certain identification procedures. Information reporting and backup withholding will not apply with respect to payments made to certain exempt recipients, such as corporations and tax-exempt organizations. Backup withholding is not an additional tax and may be claimed as a credit against the U.S. federal income tax liability of a U.S. holder, provided that the required information is furnished to the IRS.

Tax Reporting

Certain U.S. holders will be required to file an IRS Form 926 (Return by a U.S. Transferor of Property to a Foreign Corporation) to report a transfer of cash or other property to us. Substantial penalties may be imposed on a U.S. holder that fails to comply with this reporting requirement. Each U.S. holder is urged to consult with its own tax advisor regarding this reporting obligation.

Foreign Asset Reporting

Certain U.S. holders who are individuals may be required to report information relating to an interest in our ordinary shares, subject to certain exceptions. For example, certain U.S. holders that own "specified foreign financial assets" with an aggregate value in excess of $50,000 on the last day of the taxable year or $75,000 at any time during the taxable year (or such higher dollar amount as may be prescribed by applicable IRS guidance) are generally required to file IRS Form 8938 with respect to such assets with their tax returns. "Specified foreign financial assets" include any financial accounts maintained by foreign financial institutions, as well as any of the following, but only if they are not held in accounts maintained by financial institutions: (i) stocks and securities issued by non-U.S. persons; (ii) financial instruments and contracts held for investment that have non-U.S. issuers or counterparties; and (iii) interests in foreign entities. Failure to file IRS Form 8938 for each applicable taxable year may result in substantial penalties and the statute of limitations on the assessment and collection of U.S. federal income taxes of such U.S. holder for the related taxable year may not close until three years after the date on which the required information is filed. U.S. holders are urged to consult their tax advisors regarding the application of these and other reporting requirements that may apply to their ownership of ordinary shares.

Non-U.S. Holders of Ordinary Shares

Except as provided below, a non-U.S. holder of ordinary shares generally will not be subject to U.S. income or withholding tax on the payment of dividends on and the proceeds from the disposition of ordinary shares.

A non-U.S. holder may be subject to U.S. federal income tax on dividends received on ordinary shares or upon the receipt of income from the disposition of ordinary shares if: (i) such income is effectively connected with the conduct by the non-U.S. holder of a trade or business in the United States or, in the case of a resident of a country which has an applicable income tax treaty with the United States, such item is attributable to a permanent establishment or a fixed place of business of the non-U.S. holder in the United States; (ii) with respect to a U.S. holder that is an individual, the non-U.S. holder is an individual who is present in the United States for 183 days or more in the taxable year of the sale and certain other conditions are met; or (iii) the non-U.S. holder is subject to tax pursuant to the provisions of the U.S. tax laws applicable to certain former citizens or residents of the United States.

Payments to non-U.S. holders of distributions on, or proceeds from the disposition of, ordinary shares are generally exempt from information reporting and backup withholding. However, a non-U.S. holder may be required, under certain circumstances, to establish that exemption by providing certification of non-U.S. status on an appropriate IRS Form W-8.

THE DISCUSSION ABOVE IS A GENERAL SUMMARY AND IS NOT INTENDED TO CONSTITUTE A COMPLETE ANALYSIS OF ALL TAX CONSEQUENCES RELATING TO THE PURCHASE, OWNERSHIP AND DISPOSITION OF OUR ORDINARY SHARES. IT DOES NOT COVER ALL TAX MATTERS THAT MAY BE OF IMPORTANCE TO A U.S. HOLDER. EACH U.S. HOLDER IS URGED TO CONSULT ITS OWN TAX ADVISOR ABOUT THE TAX CONSEQUENCES TO IT RELATING TO THE PURCHASE, OWNERSHIP, AND DISPOSITION OF ORDINARY SHARES IN LIGHT OF THE INVESTOR'S OWN CIRCUMSTANCES.

F. Dividends and Paying Agents

Not applicable.

G. Statement by Experts

Not applicable.

H. Documents on Display

We are subject to certain information reporting requirements of the Exchange Act, applicable to foreign private issuers and under those requirements will file reports with the SEC. The SEC maintains an internet site at http://www.sec.gov that contains reports, proxy and information statements and other information regarding issuers that file electronically with the SEC. Our filings with the SEC will also be available to the public through the SEC's website at www.sec.gov.

As a foreign private issuer, we are exempt from the rules under the Exchange Act related to the furnishing and content of proxy statements, and our officers, directors and principal shareholders will be exempt from the reporting and short-swing profit recovery provisions contained in Section 16 of the Exchange Act. In addition, we are not required under the Exchange Act to file annual, quarterly and current reports and financial statements with the SEC as frequently or as promptly as U.S. domestic companies whose securities are registered under the Exchange Act. However, we will file with the SEC, within 120 days after the end of each fiscal year, or such applicable time as required by the SEC, an annual report on Form 20-F containing financial statements audited by an independent registered public accounting firm, and may submit to the SEC, on a Form 6-K, unaudited quarterly financial information.

I. Subsidiary Information.

Not applicable.

J. Annual Report to Security Holders.

Not applicable.

ITEM 11. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We are exposed to market risk in the ordinary course of our business. Market risk represents the risk of loss that may impact our financial position due to adverse changes in financial market prices and rates. Our market risk exposure is primarily a result of fluctuations in foreign currency exchange rates and interest rates.

Foreign Currency Exchange Risk

Our functional and reporting currency is the U.S. dollar. Our foreign currency exposures give rise to market risk associated with exchange rate movements of the NIS, mainly against the U.S. dollar and the Euro. A material portion of our expenses consist principally of payments in NIS made to employees, subcontractors and consultants for clinical trials, other research and development activities, and purchase of new equipment. A material portion of our research and development is conducted through collaboration agreements denominated in U.S. dollars, and therefore our net research and development expenses are subject to significant foreign currency risk. If the NIS fluctuates significantly against either the U.S. dollar or the Euro, it may have a negative impact on our results of operations.

To date, we have not entered into any hedging arrangements with respect to foreign currency risk or other derivative financial instruments. In the future, we may enter into currency hedging transactions to decrease the risk of financial exposure from fluctuations in the operating currencies. These measures, however, may not adequately protect us from the material adverse effects of such fluctuations.

Interest Rate Risk

At present, our investments consist primarily of cash and cash equivalents in short-term deposits. The primary objective of our investment activities is to preserve our capital to fund our operations. Our investments are exposed to market risk due to fluctuation in interest rates, which may affect our interest income and the fair market value of our investments, if any. We manage this exposure by performing ongoing evaluations of our investments. Due to the short-term maturities, if any, of our investments to date, their carrying value has always approximated their fair value. We believe that our exposure to interest rate risk is not significant and a 1% change in market interest rates would not have a material impact on our assets.

ITEM 12. DESCRIPTION OF SECURITIES OTHER THAN EQUITY SECURITIES

A. Debt Securities.

Not applicable.

B. Warrants and rights.

Not applicable.

C. Other Securities.

Not applicable.

D. American Depositary Shares

Not applicable.

PART II

ITEM 13. DEFAULTS, DIVIDEND ARREARAGES AND DELINQUENCIES

None.

ITEM 14. MATERIAL MODIFICATIONS TO THE RIGHTS OF SECURITY HOLDERS AND USE OF PROCEEDS

There are no material modifications to the rights of security holders.

ITEM 15. CONTROLS AND PROCEDURES

(a) Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Deputy CEO & Chief Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures (as such term is defined in Rules 13a-15(c) and 15d-15(e) under the Exchange Act) as of December 31, 2024, or the Evaluation Date. Based on such evaluation, those officers have concluded that, as of the Evaluation Date, our disclosure controls and procedures are effective in recording, processing, summarizing and reporting, on a timely basis, information required to be included in periodic filings under the Exchange Act and that such information is accumulated and communicated to management, including our principal executive and financial officers, as appropriate to allow timely decisions regarding required disclosure.

(b) Management's Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over our financial reporting. Internal control over financial reporting is defined in Rule 13a-15(f) or 15d-15(f) promulgated under the Exchange Act as a process designed by, or under the supervision of, the company's principal executive and principal financial officers and effected by the company's board of directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles and includes those policies and procedures that:

- pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transaction and dispositions of the assets of the company;
- provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and
- provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2024. In making this assessment, our management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control-Integrated Framework (2013). Based on that assessment, our management concluded that as of December 31, 2024, our internal control over financial reporting was effective.

(c) Attestation Report of the Registered Public Accounting Firm

Not applicable.

(d) Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting (as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during the period covered by this Annual Report that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 16. [RESERVED]

ITEM 16A. AUDIT COMMITTEE FINANCIAL EXPERT

Our board of directors has determined that one member of our audit committee, Dr. Elan Penn, is an audit committee financial expert, as defined under the rules under the Exchange Act, and is independent in accordance with applicable Exchange Act rules and the Nasdaq Listing Rules.

ITEM 16B. CODE OF ETHICS

Our board of directors has adopted a Code of Business Conduct and Ethics applicable to all of our directors and employees, including our Chief Executive Officer, Chief Financial Officer, controller or principal accounting officer, or other persons performing similar functions, which is a "code of ethics" as defined in Item 16B of Form 20-F promulgated by the SEC. The full text of the Code of Business Conduct and Ethics is posted on our website at *www.CollPlant.com*. Information contained on, or that can be accessed through, our website does not constitute a part of this a part of this Annual Report on Form 20-F and is not incorporated by reference herein. In November 2023, our board of directors adopted an amendment to our Code of Business Conduct and Ethics, focusing on Environmental, Governance and Corporate (ESG) aspects, to strengthen our dedication to responsible business conduct and aligning with current governance best practices. If we make any amendment to the Code of Business Conduct and Ethics or grant any waivers, including any implicit waiver, from a provision of the Code of Business Conduct and Ethics, we will disclose the nature of such amendment or waiver on our website to the extent required by the rules and regulations of the SEC. We have not granted any waivers under our Code of Business Conduct and Ethics.

ITEM 16C. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The following table provides information regarding fees paid by us to Kost Forer Gabbay and Kasierer and/or other member firms of Ernst and Young Global and to Kesselman & Kesselman and/or other member firms of PricewaterhouseCoopers International Limited for all services, including audit services, for the years ended December 31, 2024 and 2023:

	2024	2023
(USD in thousands)		
Audit fees[(1)]	317	261
Tax fees[(2)]		12
All other fees	8	63
Total	325	336

(1) The audit fees for the years ended December 31, 2024 and 2023 includes professional services rendered in connection with the audit of our annual consolidated financial statements and the review of our consolidated interim financial statements, statutory audits of the Company and its subsidiaries, issuance of consents and assistance with review of documents filed with the SEC.

(2) Tax fees for the years ended December 31, 2024 and 2023 were for services related to tax advice, including assistance with tax audit.

Pre-Approval of Auditors' Compensation

Our audit committee has a pre-approval policy for the engagement of our independent registered public accounting firm to perform certain audit and non-audit services. Pursuant to this policy, which is designed to assure that such engagements do not impair the independence of our auditors, the audit committee pre-approves annually a catalog of specific audit and non-audit services in the categories of audit services, audit-related services and tax services that may be performed by our independent registered public accounting firm. If a type of service, that is to be provided by our auditors, has not received such general pre-approval, it will require specific pre-approval by our audit committee. The policy prohibits retention of the independent registered public accounting firm to perform the prohibited non-audit functions defined in applicable SEC rules.

ITEM 16D. EXEMPTIONS FROM THE LISTING STANDARDS FOR AUDIT COMMITTEES

Not applicable.

ITEM 16E. PURCHASES OF EQUITY SECURITIES BY THE ISSUER AND AFFILIATED PURCHASERS

Not applicable.

ITEM 16F. CHANGE IN REGISTRANT'S CERTIFYING ACCOUNTANT

Not applicable.

ITEM 16G. CORPORATE GOVERNANCE

Under the Companies Law, companies incorporated under the laws of the State of Israel, whose shares are publicly traded, including companies whose shares are listed on the Nasdaq Global Market are considered public companies under Israeli law and are required to comply with various corporate governance requirements under Israeli law relating to such matters as external directors, the audit committee, compensation committee, compensation policy, company's auditors, and an internal auditor. These requirements are in addition to the corporate governance requirements imposed by the Nasdaq Listing Rules, and other applicable provisions of U.S. securities laws to which we are subject as a foreign private issuer due to the listing of our ordinary shares on the Nasdaq Global Market. However, pursuant to regulations promulgated under the Companies Law, companies with shares traded on certain U.S. stock exchanges, including the Nasdaq Global Market, may, subject to certain conditions, "opt out" from the requirement of the Companies Law to appoint external directors (*i.e.*, adopt the Exemption) and related Companies Law rules concerning the composition of the audit committee and compensation committee of the board of directors (other than the gender diversification rule under the Companies Law which requires the appointment of a director from the other gender if, at the time a director is appointed, all members of the board of directors are of the same gender). In accordance with these regulations, we have elected to "opt out" from such requirements of the Companies Law. For further information, see "Item 6.C. – Board Practices - Board of Directors". Under these regulations, the exemptions from such Companies Law's requirements will continue to be available to us so long as we comply with the following: (i) we do not have a "controlling shareholder" (as such term is defined under the Companies Law), (ii) our shares are traded on certain U.S. stock exchanges, including the Nasdaq Global Market, and (iii) we comply with the director independence requirements and the requirements regarding the composition of the audit committee and the compensation committee under U.S. laws (including applicable Nasdaq rules) applicable to U.S. domestic issuers.

Under the Nasdaq Listing Rules, a foreign private issuer, such as us, may generally follow its home country rules of corporate governance in lieu of the comparable requirements of the Nasdaq Global Market, except for certain matters including (among others) the composition and responsibilities of the audit committee and the independence of its members within the meaning of the rules and regulations of the SEC.

We intend to rely on this "home country practice exemption" with respect to the following Nasdaq Listing Rules:

- ***Quorum requirements.*** As permitted under the Companies Law pursuant to our articles of association, the quorum required for an ordinary meeting of shareholders will consist of at least two shareholders present in person, by proxy or by other voting instrument in accordance with the Companies Law, who hold at least 20% of the voting power of our shares (and in an adjourned meeting, with some exceptions, any number of participating shareholders), instead of $33^{1}/_{3}\%$ of the issued share capital required under the Nasdaq Listing Rules.

- ***Distribution of certain reports to shareholders.*** As opposed to the Nasdaq Listing Rules, which require listed issuers to make its annual reports available to shareholders in one of a number of specific manners, Israeli law does not require that we distribute annual reports, including our financial statements. As such, the generally accepted business practice in Israel is to distribute such reports to shareholders through a public regulated distribution website. In addition to making such reports available on a public regulated distribution website, we plan to make our audited financial statements available to our shareholders at our offices and will only mail such reports to shareholders upon request. As a foreign private issuer, we are generally exempt from the SEC's proxy solicitation rules.

- ***Shareholder approval.*** We will seek shareholder approval for all corporate actions requiring such approval under the requirements of the Companies Law, rather than seeking approval for corporate actions in accordance with Nasdaq Listing Rule 5635. In particular, under this Nasdaq Listing Rule, shareholder approval is generally required for: (i) an acquisition of shares or assets of another company that involves the issuance of 20% or more of the acquirer's shares or voting rights or if a director, officer or 5% shareholder has greater than a 5% interest in the target company or the consideration to be received; (ii) the issuance of shares leading to a change of control; (iii) adoption or amendment of equity compensation arrangements; and (iv) issuances of 20% or more of the shares or voting rights (including securities convertible into, or exercisable for, equity) of a listed company via a private placement (or via sales by directors, officers or 5% shareholders) if such equity is issued (or sold) at below the greater of the book or market value of shares. By contrast, under the Companies Law, shareholder approval is required (subject to certain limited exceptions) for, among other things: (a) transactions with directors concerning the terms of their service (including indemnification, exemption, and insurance for their service or for any other position that they may hold at a company), for which approvals of the compensation committee, board of directors, and shareholders are all required; (b) extraordinary transactions with controlling shareholders of publicly held companies, which require the special approval described below under "Disclosure of Personal Interests of Controlling Shareholders and Approval of Certain Transactions;" (c) terms of office and employment or other engagement of our controlling shareholder, if any, or such controlling shareholder's relative, which require the special approval described below under "Disclosure of Personal Interests of Controlling Shareholders and Approval of Certain Transactions;" (d) approval of transactions with Company's Chief Executive Officer with respect to his or hers compensation, whether in accordance with the approved compensation policy of the Company or not in accordance with the approved compensation policy of the Company, or transactions with officers of the Company not in accordance with the approved compensation policy; and (e) approval of the compensation policy of the Company for office holders. In addition, under the Companies Law, a merger requires approval of the shareholders of each of the merging companies.

Except as stated above, we intend to comply with the rules generally applicable to U.S. domestic companies listed on the Nasdaq Global Market. We may in the future decide to use other foreign private issuer exemptions with respect to some or all of the other Nasdaq Listing Rules. Following our home country governance practices, as opposed to the requirements that would otherwise apply to a company listed on the Nasdaq Global Market, may provide less protection than is accorded to investors under the Nasdaq Listing Rules applicable to domestic issuers.

ITEM 16H. MINE SAFETY DISCLOSURE

Not applicable.

ITEM 16I. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

Not applicable.

ITEM 16J. INSIDER TRADING POLICIES

We have adopted a statement of trading policies that governs the trading in our securities by our directors, officers and certain other covered persons, and which is reasonably designed to promote compliance with applicable insider trading laws, rules and regulations, and any listing standards applicable to the Company. A copy of the Insider Trading Policy is included as Exhibit 11.1 to this annual report. In addition, with regard to any trading in our own securities, it is our policy to comply with the federal securities laws and the applicable exchange listing requirements.

ITEM 16K. CYBERSECURITY

We have developed and maintain a cybersecurity risk management program, consisting of cybersecurity policies, procedures, compliance and awareness programs to mitigate risk and to ensure compliance with security, availability and confidentiality trust principles. The cybersecurity process has been integrated into our overall risk management system and process, and is solely internally managed. Management is responsible for identifying risks that threaten achievement of the control activities stated in the management's description of the services organizations systems. Management has implemented a process for identifying relevant risks that could affect the organization's ability to provide secure and reliable service to its users. The risk assessment occurs annually, or as business needs change, and covers identification of risks that could act against the Company's objectives as well as specific risks related to a compromise to the security of data. See "Item 3.D — Risk Factors — Risks Related to Our Business Operations— Our business and operations would suffer in the event of computer system failures or security breaches."

The level of each identified risk is determined by considering the impact of the risk itself and the likelihood of the risk materializing and high scoring risks are actioned upon. Risks are analyzed to determine whether the risk meets Company risk acceptance criteria to be accepted or whether a mitigation plan will be applied. Mitigation plans include both the individual or department responsible for the plan and may include budget considerations.

The oversight of cybersecurity threats is undertaken by our information technology manager, supported by our management and external professional consultants. Our management is responsible for cybersecurity oversight and monitoring risk.

As of the date of this report, we have not, to our knowledge, experienced any material IT system failures or any material cybersecurity attacks, and we are not aware of any material risks from cybersecurity threats that have materially affected or are reasonably likely to materially affect us, including our business strategy, results of operations or financial condition.

PART III

ITEM 17. FINANCIAL STATEMENTS

We have elected to provide financial statements and related information pursuant to Item 18.

ITEM 18. FINANCIAL STATEMENTS

The consolidated financial statements and the related notes required by this Item are included in this Annual Report on Form 20-F beginning on page F-1.

ITEM 19. EXHIBITS.

Exhibit No.	Exhibit Description
1.1	Memorandum of Association of the Company (unofficial English translation from Hebrew original) (included as Exhibit 3.1 to our Registration Statement on Form F-1 as filed with the Securities and Exchange Commission on October 21, 2016, and incorporated herein by reference).
1.2	Amended and Restated Articles of Association of the Company, as currently in effect (unofficial English translation from Hebrew original). (included as Exhibit 1.2 to our Annual Report on Form 20-F filed with the Securities and Exchange Commission on March 26, 2021, and incorporate herein by reference)
2.1*	Description of Securities Registered under Section 12.
4.1	Form of Letter of Indemnification Agreement (included as Exhibit A to Exhibit 99.1 to our Report on Form 6-K filed with the Securities and Exchange Commission on June 8, 2023, and incorporated herein by reference)
4.2	Form of Letter of Exemption ((unofficial English translation from Hebrew original) (included as Exhibit 10.1 to our Registration Statement on Form F-1 as filed with the Securities and Exchange Commission on October 21, 2016, and incorporated herein by reference)
4.3†	Agreement, dated July 13, 2004, by and among Meytav—Technological Innovation Center Ltd., Yehuda Zafrir Fagin, Yissum Research Development Company of the Hebrew University of Jerusalem Ltd., or Yissum, and Prof. Oded Shoseyov (includes unofficial English translation of certain exhibits from Hebrew original) (included as Exhibit 10.2 to our Registration Statement on Form F-1 as filed with the Securities and Exchange Commission on October 21, 2016, and incorporated herein by reference)
4.4#*	Employee Share Ownership and Option Plan (2010) (as amended)) (included as Exhibit 4.3 to our Annual Report on Form 20-F as filed with the Securities and Exchange Commission on April 4, 2024, and incorporated herein by reference)
4.5#*	Employee Share Ownership and Option Plan (2024) (included as Exhibit 4.4 to our Annual Report on Form 20-F as filed with the Securities and Exchange Commission on April 4, 2024, and incorporated herein by reference)
4.6#	Employment Agreement dated September 30, 2009 between CollPlant Ltd. and Yehiel Tal (includes unofficial English translation of an exhibit from Hebrew original) (included as Exhibit 10.5 to our Registration Statement on Form F-1 as filed with the Securities and Exchange Commission on October 21, 2016, and incorporated herein by reference)
4.7#	Employment Agreement dated October 30, 2011 between CollPlant Ltd. and Eran Rotem (includes unofficial English translation of certain exhibits from Hebrew original) (included as Exhibit 10.6 to our Registration Statement on Form F-1 as filed with the Securities and Exchange Commission on October 21, 2016, and incorporated herein by reference)
4.8	Waiver dated September 10, 2017 to Agreement, dated July 13, 2004, by and among Meytav—Technological Innovation Center Ltd., Yehuda Zafrir Fagin, Yissum Research Development Company of the Hebrew University of Jerusalem Ltd., or Yissum, and Prof. Oded Shoseyov (included as Exhibit 10.8 to our Amendment No. 3 to the Registration Statement on Form F-1 as filed with the Securities and Exchange Commission on November 22, 2017, and incorporated herein by reference)
4.9†	Rental Agreement, dated November 15, 2018, as amended (unofficial English translation from Hebrew original) (included as Exhibit 4.24 to our Annual Report on Form 20-F as filed with the Securities and Exchange Commission on April 1, 2019, and incorporated herein by reference)
4.10	Form of Securities Purchase Agreement dated as of February 11, 2021 by and between the Company and the Purchasers named therein (included as Exhibit 10.1 to our Report on Form 6-K filed with the Securities and Exchange Commission on February 17, 2021, and incorporated herein by reference)

4.11#	Amended and Restated Compensation Policy (included as Exhibit B to Exhibit 99.1 to our Report on Form 6-K filed with the Securities and Exchange Commission on June 8, 2023, and incorporated herein by reference)
8.1	Subsidiaries of the Company (included as Exhibit 8.1 to our Annual Report on Form 20-F as filed with the Securities and Exchange Commission on March 24, 2022, and incorporated herein by reference)
11.1*	Insider Trading Policy
12.1*	Certification of the Chief Executive Officer pursuant to rule 13a-14(a) of the Securities Exchange Act of 1934
12.2*	Certification of the Chief Financial Officer pursuant to rule 13a-14(a) of the Securities Exchange Act of 1934
13.1*	Certification of the Chief Executive Officer pursuant to 18 U.S.C. 1350
13.2*	Certification of the Chief Financial Officer pursuant to 18 U.S.C. 1350
15.1*	Consent of Kost Forer Gabbay & Kasierer, a member firm of Ernst & Young Global, Independent Registered Public Accounting Firm.
97.1#	Clawback Policy (included as Exhibit A to Exhibit B to Exhibit 99.1 to our Report on Form 6-K filed with the Securities and Exchange Commission on June 8, 2023, and incorporated herein by reference)
101.INS	Inline XBRL Instance Document
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (formatted as Inline iXBRL and contained in Exhibit 101).

* Filed herewith.

† Portions of this exhibit have been omitted and filed separately with the Securities and Exchange Commission pursuant to a confidential treatment request.

Management contract or compensatory plan.

SIGNATURES

The registrant hereby certifies that it meets all of the requirements for filing on Form 20-F and that it has duly caused and authorized the undersigned to sign this Annual Report on Form 20-F filed on its behalf.

COLLPLANT BIOTECHNOLOGIES LTD.

Date: March 26, 2025

By: /s/ Eran Rotem
Eran Rotem
Deputy CEO and Chief Financial Officer

COLLPLANT BIOTECHNOLOGIES LTD.
FINANCIAL STATEMENTS

AS OF DECEMBER 31, 2024

U.S. DOLLARS IN THOUSANDS

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Report of Independent Registered Public Accounting Firm

To the Shareholders and the Board of Directors of

CollPlant Biotechnologies Ltd.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of CollPlant Biotechnologies Ltd. (the Company) as of December 31, 2024 and 2023, the related consolidated statements of operations, shareholders' equity and cash flows for each of the three years in the period ended December 31, 2024, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2024 and 2023, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2024, in conformity with U.S. generally accepted accounting principles.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current period audit of the financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective or complex judgments. The communication of the critical audit matter does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Liquidity and Capital Resources

Description of the Matter	As discussed in Note 1 to the consolidated financial statements, the Company has incurred operating losses and negative cash-flow from operations since inception. The Company's operations are dependent on its ability to raise additional funds. This dependency will continue until the Company is able to completely finance its operations by generating revenue from its product candidates. Also, the Company's Board approved a contingency plan, to be implemented if needed, in whole or in part, at its discretion, to allow the Company to continue its operations and meet its cash obligations. The contingency plan consists of cost reduction, which include mainly the following steps: reduction in subcontractors' expenses, headcount and compensation paid to key management. Management has concluded that, based on its current projections and plans, the Company will be able to satisfy its liquidity requirements for at least twelve months from the date these financial statements were issued. Auditing the assessment of liquidity and the Company's ability to continue as a going concern was subjective due to the judgments required of management to conclude the Company would have sufficient liquidity to sustain itself for at least twelve months beyond the date of the issuance of the consolidated financial statements. This in turn led to a high degree of auditor judgment to evaluate the audit evidence supporting the liquidity conclusions
How We Addressed the Matter in Our Audit	To test the assessment of liquidity and the Company's ability to continue as a going concern our audit procedures included, testing the completeness, accuracy, and relevance of underlying data used in the Company's assessment; evaluating the reasonableness of the assumptions included in the forecasted cash flows used by management, including; evaluating whether the underlying assumptions were reasonable considering the Company's current and past performance, and whether these assumptions were consistent with evidence obtained in other areas of the audit. We also compared the Company's historical forecast to its actual results to assess the Company's ability to accurately forecast and assessed the sensitivity and impact of reasonably possible changes in the key assumptions and estimates included in management's cash flow forecasts and liquidity position. In addition, we assessed the adequacy of the company's liquidity and capital resources disclosures included in note 1 to the consolidated financial statements.

/s/ Kost Forer Gabbay & Kasierer

A Member of EY Global

We have served as the Company's auditor since 2020.

Tel-Aviv, Israel

March 26, 2025

COLLPLANT BIOTECHNOLOGIES LTD.
CONSOLIDATED BALANCE SHEETS
(U.S. dollars in thousands)

	December 31,	
	2024	**2023**
Assets		
Current assets:		
Cash and cash equivalents	$ 11,909	$ 26,674
Restricted deposit	248	241
Trade receivables, net	150	-
Inventories	440	714
Other accounts receivable and prepaid expenses	433	393
Total current assets	13,180	28,022
Non-current assets:		
Restricted deposit	118	57
Operating lease right-of-use assets	2,991	3,070
Property and equipment, net	2,290	2,789
Intangible assets, net	131	188
Total non-current assets	5,530	6,104
Total assets	$ 18,710	$ 34,126

The accompanying notes are an integral part of the consolidated financial statements.

COLLPLANT BIOTECHNOLOGIES LTD.
CONSOLIDATED BALANCE SHEETS
(U.S. dollars in thousands, except share data)

	December 31,	
	2024	**2023**
Liabilities and shareholders' equity		
Current liabilities:		
Trade payables	$ 870	$ 980
Operating lease liabilities	806	624
Accrued liabilities and other payables	1,294	1,647
Total current liabilities	2,970	3,251
Non-current liabilities:		
Operating lease liabilities	2,275	2,535
Total non-current liabilities	2,275	2,535
Total liabilities	5,245	5,786
Commitments and contingencies		
Shareholders' Equity:		
Ordinary shares, NIS 1.5 par value - authorized: 30,000,000 ordinary shares as of December 31, 2024 and 2023; issued and outstanding: 11,454,512 and 11,452,672 ordinary shares as of December 31, 2024 and 2023, respectively	4,983	4,982
Additional paid in capital	122,801	121,068
Accumulated other comprehensive loss	(969)	(969)
Accumulated deficit	(113,350)	(96,741)
Total shareholders' equity	13,465	28,340
Total liabilities and shareholders' equity	$ 18,710	$ 34,126

The accompanying notes are an integral part of the consolidated financial statements.

COLLPLANT BIOTECHNOLOGIES LTD.
CONSOLIDATED STATEMENTS OF OPERATIONS
(U.S. dollars in thousands, except share and per share data)

	Year ended December 31,		
	2024	**2023**	**2022**
Revenues	$ 515	$ 10,959	$ 299
Cost of revenues	1,625	1,991	400
Gross profit (loss)	(1,110)	8,968	(101)
Operating expenses:			
Research and development	10,515	10,484	10,255
General, administrative and marketing	5,626	5,996	6,741
Total operating loss	(17,251)	(7,512)	(17,097)
Financial income, net	642	493	172
Net loss	$ (16,609)	$ (7,019)	$ (16,925)
Basic and diluted net loss per ordinary share	$ (1.45)	$ (0.62)	$ (1.53)
Weighted average number of ordinary shares used in computation of basic and diluted net loss per share	11,454,180	11,389,168	11,033,310

The accompanying notes are an integral part of the consolidated financial statements.

COLLPLANT BIOTECHNOLOGIES LTD.
CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY
(U.S. dollars in thousands, except share data)

	Ordinary shares		Additional paid-in	Accumulated other comprehensive	Accumulated	
	Number	Amounts	capital	loss	deficit	Total
BALANCE AT DECEMBER 31, 2021	10,722,024	$ 4,664	$ 114,223	$ (969)	$ (72,797)	$ 45,121
Exercise of warrants	425,000	191	1,509	-	-	1,700
Exercise of options	39,457	18	156	-	-	174
Share-based compensation	-	-	2,211	-	-	2,211
Net loss	-	-	-	-	(16,925)	(16,925)
BALANCE AT DECEMBER 31, 2022	11,186,481	$ 4,873	$ 118,099	$ (969)	$ (89,722)	$ 32,281
Exercise of warrants	186,000	76	668	-	-	744
Exercise of options	80,191	33	331	-	-	364
Share-based compensation	-	-	1,970	-	-	1,970
Net loss	-	-	-	-	(7,019)	(7,019)
BALANCE AT DECEMBER 31, 2023	11,452,672	$ 4,982	$ 121,068	$ (969)	$ (96,741)	$ 28,340
Exercise of options	1,840	1	8	-	-	9
Share-based compensation	-	-	1,725	-	-	1,725
Net loss	-	-	-	-	(16,609)	(16,609)
BALANCE AT DECEMBER 31, 2024	11,454,512	$ 4,983	$ 122,801	$ (969)	$ (113,350)	$ 13,465

The accompanying notes are an integral part of the consolidated financial statements.

COLLPLANT BIOTECHNOLOGIES LTD.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(U.S. dollars in thousands)

	Year ended December 31,		
	2024	**2023**	**2022**
Cash flows from operating activities:			
Net loss	$ (16,609)	$ (7,019)	$ (16,925)
Adjustments to reconcile net loss to net cash used in operating activities:			
Loss on sale of property and equipment	-	18	-
Depreciation and amortization	1,038	1,102	1,076
Accrued interest	(11)	(28)	(87)
Share-based compensation to employees and consultants	1,719	1,937	2,174
Exchange differences on cash and cash equivalents and restricted cash	142	379	608
Changes in assets and liabilities:			
Decrease (increase) in trade receivables	(150)	9	261
Decrease (increase) in inventories	280	749	(312)
Decrease (increase) in other receivables and prepaid expenses	(40)	150	(119)
Decrease in operating lease right-of-use assets	651	527	461
Increase (decrease) in trade payables	(110)	(153)	99
Decrease in operating lease liabilities	(650)	(638)	(916)
Increase in accrued liabilities and other payables	(353)	204	14
Decrease in deferred revenues	-	-	(32)
Net cash used in operating activities	(14,093)	(2,763)	(13,698)
Cash flows from investing activities:			
Capitalization of intangible assets	-	-	(42)
Purchase of property and equipment	(483)	(954)	(1,274)
Proceed from short term deposit	-	-	50,238
Investment in restricted deposits	(57)	(270)	-
Investment in deposits	-	-	(20,000)
Proceeds from sale of property and equipment	1	68	-
Net cash provided by (used in) investing activities	(539)	(1,156)	28,922
Cash flows from financing activities:			
Exercise of options and warrants into shares	9	1,108	1,874
Net cash provided by financing activities	9	1,108	1,874
Effect of exchange rate changes on cash and cash equivalents and restricted deposits	(142)	(379)	(608)
Net increase (decrease) in cash and cash equivalents	(14,765)	(3,190)	16,490
Cash and cash equivalents at the beginning of the year	26,674	29,864	13,374
Cash and cash equivalents at the end of the year	$ 11,909	$ 26,674	$ 29,864

COLLPLANT BIOTECHNOLOGIES LTD.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(U.S. dollars in thousands)

	Year ended December 31,		
	2024	2023	2022
Supplemental discloser of non-cash activities:			
Right of use assets recognized with corresponding lease liabilities	$ 572	$ 886	$ 219
Capitalization of Share-based compensation to inventory	$ 6	$ 33	$ 37
Supplemental discloser of cash activities:			
Cash paid during the year for taxes	$ 62	$ 8	$ 31

The accompanying notes are an integral part of the consolidated financial statements.

NOTE 1 - GENERAL

Company description

a. CollPlant Biotechnologies Ltd. (the "Company" or "CollPlant") is a regenerative and aesthetic medicine company focused on 3D bioprinting of tissues and organs and medical aesthetics. The Company's products are based on its rhCollagen (recombinant human collagen) produced with CollPlant's proprietary plant-based technology. These products address indications for the diverse fields of tissue repair, aesthetics, and organ manufacturing.

The Company's revenues include income from business collaborators and from sales of (i) bioink products for the development of 3D bioprinting of organs and tissues, (ii) rhCollagen for the medical aesthetics market, and (iii) rhCollagen-based products for tendinopathy and wound care.

The Company operates mainly through its wholly-owned subsidiary CollPlant Ltd. In November 2021 CollPlant Ltd. established CollPlant Inc., a wholly owned subsidiary in the United States. As of December 31, 2024, CollPlant Inc. has not commenced operation.

b. For the year ended December 31, 2024, the Company incurred net loss of $16,609 and has an accumulated deficit in the total amount of $113,350. The Company's negative cash flows from operating activities was $14,093. The Company's cash and cash equivalent as of December 31, 2024 totaled $11,909. The Company expects to incur future net losses and the transition to profitability is dependent upon, among other things, the successful development and commercialization of the Company's products and product candidates or, of the dermal filler product developed by AbbVie, the establishment of contracts for the distribution of new product lines, any of which, or in combination, would contribute to the achievement of a level of revenue adequate to support the cost structure. Until the Company achieves profitability or generates positive cash flows, it will continue to need to raise additional cash to finance its operations and to fund future operations through existing cash on hand, additional private and/or public offerings of debt or equity securities, additional milestone payments that may be received under the AbbVie Development Agreement. Notwithstanding, there can be no assurance that the Company will be able to raise additional funds or achieve or sustain profitability or positive cash flows from operation, and even if available, whether it will be on terms acceptable to the Company or in amounts required.
Accordingly, the Company's Board approved a contingency plan, to be implemented if needed, in whole or in part, at its discretion, to allow the Company to continue its operations and meet its cash obligations. The contingency plan consists of cost reduction, which include mainly the following steps: reduction in subcontractors' expenses, headcount and compensation paid to key management. The Company and the Board believe that its existing capital resources will be adequate to satisfy its expected liquidity requirements for at least twelve months from the filing date.

NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES

a. Basis of presentation of the financial statements

The accompanying consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States ("U.S GAAP").

b. Use of estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. The Company's management believes that the estimates, judgment and assumptions used are reasonable based upon information available at the time they are made. Actual results may differ from those estimates.

c. Financial statements in U.S. dollars:

The functional currency is the currency that best reflects the economic environment in which the Company and its subsidiaries operates and conducts their transactions. Most of the Company's revenues and financing activity are incurred in U.S. dollar. Based on the Company's management assessment the functional currency of the Company is the U.S. dollar.

Transactions and balances that are denominated in currencies other than the U.S. dollar are remeasured into U.S. dollars in accordance with principles set forth in ASC 830, Foreign Currency Matters ("ASC 830"). In accordance with ASC 830, monetary assets and liabilities denominated in foreign currencies are remeasured into U.S. dollars at the end of each reporting period using the exchange rates in effect at the balance sheet date. Non-monetary assets denominated in foreign currencies are measured using historical exchange rates. Gains and losses resulting from remeasurement are reflected in the statements of operation as financial income or expenses, as appropriate.

d. Principles of consolidation

The consolidated financial statements include the accounts of the Company and its subsidiaries. All inter-company transactions and balances have been eliminated in consolidation.

NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES (continued)

e. Segments

The Company operates as one operating segment. Operating segments are defined as components of an enterprise for which separate financial information is regularly evaluated by the CODM, which is the Company's chief executive officer, in deciding how to allocate resources and assess performance. The Company's CODM evaluates the Company's financial information and resources and assesses the performance of these resources on a consolidated basis. There is no expense or asset information, that are supplemental to those disclosed in these consolidated financial statements, that are regularly provided to the CODM. The allocation of resources and assessment of performance of the operating segment is based on consolidated net loss as shown in the Company's consolidated statements of operations. The CODM considers net loss in the annual forecasting process and reviews actual results when making decisions about allocating resources. Since the Company operates as one operating segment, financial segment information, including profit or loss and asset information, can be found in the consolidated financial statements.

f. Cash and cash equivalents

The Company considers as cash equivalents all short-term, highly liquid investments, which include short-term bank deposits with original maturities of three months or less from the date of purchase that are not restricted as to withdrawal or use and are readily convertible to known amounts of cash.

g. Restricted deposits

The Company's restricted deposits long term and short term collaterals related to the Company's lease contracts and credit card.

h. Trade receivables, net

Trade receivables are recorded net of credit losses allowance for any potential uncollectible amounts. The allowance for credit losses is based on the Company's assessment of the collectability of accounts. The Company regularly assessed collectability based on a combination of factors, including an assessment of the current customer's aging balance, the nature and size of the customer, the financial condition of the customer, estimate of future conditions and other factors that may affect its ability to collect from customers.

i. Inventories

Inventories are stated at the lower of cost or net realizable value.

Inventory costing is based on the moving average cost method. In the case of purchased goods and work in process, costs include raw materials, direct labor, share based compensation and other direct costs and fixed production overheads (based on the normal operating capacity of the production facilities). The Company periodically evaluates the quantities on hand relative to historical, current and projected sales volume. Based on this evaluation, an impairment charge is recorded when required to write-down inventory to its net realizable value.

Net realizable value is the estimated selling price in the ordinary course of business, less attributable selling expenses.

NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES (continued)

j. Leases

The Company determines if an arrangement is a lease at inception. Balances related to operating leases are included in operating lease right-of-use ("ROU") assets and current and non-current operating lease liabilities in the consolidated balance sheets.

ROU assets represent the Company's right to use an underlying asset for the lease term and lease liabilities represent the Company's obligation to make lease payments arising from the lease. Operating lease ROU assets and liabilities are recognized as of the commencement date based on the present value of lease payments over the lease term. Lease terms may include options to extend or terminate the lease when it is reasonably certain that the Company will exercise that option. The Company's uses its estimated incremental borrowing rate based on the information available at the commencement date in determining the present value of lease payments. Lease expense for lease payments is recognized on a straight-line basis over the lease term. The Company elected to not recognize a lease liability or ROU asset for leases with a term of twelve months or less. The Company also elected the practical expedient to not separate lease and non-lease components for its leases (see also Note 5).

k. Property and equipment

Property and equipment are stated at cost, net of accumulated depreciation.

The Company's property and equipment are depreciated by the straight-line method on the basis of their estimated useful life.

The depreciation period is as follows:

	Years
Laboratory and production equipment	5
Greenhouse equipment*	4 - 10
Computer equipment	3
Office furniture	17
Leasehold improvements	**
Electronic equipment	7
Vehicles	7

* Greenhouse equipment - agricultural equipment used in the tobacco production greenhouse.

** Leasehold improvements are amortized by the straight-line method over the shorter of the lease term or useful economic life.

NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES (continued)

l. Impairment of long-lived assets

The Company's long-lived assets are reviewed for impairment in accordance with ASC 360, "Property, Plant and Equipment" ("ASC 360"), whenever events or changes in circumstances indicate that the carrying amount of the asset may not be recoverable. Recoverability of an asset to be held and used is measured by a comparison of the carrying amount of an asset to the future undiscounted cash flows expected to be generated by the asset. If such asset is considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the asset exceeds its fair value.

As of December 31, 2024, 2023 and 2022, the Company did not recognize an impairment loss for its long-lived assets.

m. Intangible assets

The Company capitalizes development costs incurred during the application development stage that are related to internal use technology. Under ASC 350-40, internal-use software capitalization begins when the preliminary project stage is complete and ceases at the point in which the project is substantially complete and is ready for its intended purpose.

Cost capitalized to internal use software include sub-contractors services and employee salary expenses.

n. Share-based compensation

The Company accounts for employees', directors' and consultants' share-based payment awards classified as equity awards using the grant-date fair value. The fair value of each share option award is estimated on the grant date using the Black-Scholes option-pricing model. The Black-Scholes option-pricing model requires the input of highly subjective assumptions, including the fair value of the underlying ordinary shares, the expected term of the share option, the expected volatility of the price of the company's ordinary shares, risk-free interest rates, and the expected dividend yield of ordinary shares. The assumptions used to determine the fair value of the option awards represent management's best estimates. The Company measures the grant date fair value of its restricted share units ("RSU") based on the closing market price of the ordinary share on the date of grant.

The Company elected to recognize compensation costs for awards conditioned only on continued service that have a graded vesting schedule using the accelerated method based on the multiple-option award approach.

The Company elected to account for forfeitures as they occur.

o. Research and development expenses

Research and development expenses include costs directly attributable to the conduct of research and development programs, including the cost of salaries, share-based compensation expenses, payroll taxes and other employee benefits, lab expenses, consumable materials and equipment and consulting fees. All costs associated with research and developments are expensed as incurred.

NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES (continued)

p. Revenue recognition

Revenues are recognized in accordance with ASC 606; revenue from contracts with customers is recognized when control of the promised goods or services is transferred to the customers, in an amount that the Company expects in exchange for those goods or services.

The Company recognizes revenue under the core principle that transfer of control to the Company's customers should be depicted in an amount reflecting the consideration the Company expects to receive in revenue. In order to achieve that core principle, the Company applies the following five-step approach:

(1) Identify the contract with a customer

A contract is an agreement between two or more parties that creates enforceable rights and obligations. In evaluating the contract, the Company analyzes the customer's intent and ability to pay the amount of promised consideration and considers the probability of collecting substantially all of the consideration.

(2) Identify the performance obligations in the contract

At a contract's inception, the Company assesses the goods or services promised in a contract with a customer and identifies the performance obligations.

Performance obligations are promised goods or services in a contract to transfer a distinct good or service to the customer.

The Company evaluates whether options granted to a customer to acquire additional goods or services give rise to a performance obligation. If an agreement contains such option, the Company determines that the option is a separate performance obligation only if the option provides a material right to the customer that it would not receive without entering into that agreement.

(3) Determine the transaction price

The Company estimates the transaction price based on the amount of consideration the Company expects to be received for transferring the promised goods or services in the contract. The consideration may include both fixed consideration and variable consideration. At the inception of each arrangement that includes variable consideration, the Company evaluates the amount of the potential payments and the likelihood that the payments will be received. If it is probable that a significant revenue reversal would not occur, the variable consideration is included in the transaction price.

The Company has elected to apply the practical expedient for financing component for transactions in which the difference between the payment date and the revenue recognition timing is up to 12 months.

(4) Allocate the transaction price to the performance obligations in the contract

For contracts with more than one performance obligation the Company allocates the transaction price to each separate performance obligation, based on its relative standalone selling price.

NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES (continued)

(5) Recognize revenue when a performance obligation is satisfied

Revenue is recognized when or as performance obligations are satisfied by transferring control of a promised good or service to a customer. Control either transfers over time or at a point in time, which affects when revenue is recorded.

Up-front payments and fees are recorded as deferred revenue upon receipt or when due until the Company performs its obligations under these arrangements.

The Company elected to apply the optional exemption under paragraph ASC 606-10-50-14(a) not to disclose the remaining performance obligations that relate to contracts with an original expected duration of one year or less. As of the year ended December 31, 2024 and 2023, the company did not have remaining performance obligations that relate to contracts with customers.

Revenue is recognized net of any taxes collected from customers which are subsequently remitted to governmental entities.

Trade receivables are recorded at the amount of gross billings the Company is responsible to collect.

Payment terms and conditions vary by contract type, although terms generally include requirement to pay the consideration in advance, but may be up to 60 days for certain customers.

1. Revenues from sale of goods

   The goods are the Company's rhCollagen and rhCollagen-based products, and include the bioink products for the development of 3D bioprinting of organs and tissues and the medical aesthetics and products for tendinopathy and wound care. The Company recognizes revenues from selling goods at a point in time when control over the product is transferred to customers.

2. Revenues from rendering services

   Revenue from rendering of services is recognized over time, during the period the customer simultaneously receives and consumes the benefits provided by the Company's performance. Under the Company's service contracts, the Company has a right to consideration from the customer in an amount that corresponds directly with the value to the customer of the Company's performance completed to date and recognizes revenue in the amount to which the Company has a right to invoice.

   The Company charges its customers based on payment terms agreed upon in specific agreements.

   As of December 31, 2024 and 2023, the Company did not recognize revenue from rendering services.

NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES (continued)

3. Revenues from licensing agreement

On February 5, 2021, the Company entered into development and global commercialization agreement (the "AbbVie Development Agreement"), with Allergan, an AbbVie company, pursuant to which the Company and AbbVie agreed to collaborate in the development and commercialization of dermal and soft tissue filler products for the medical aesthetics market, using the Company's rhCollagen technology and AbbVie's technology (see also Note 7).

Pursuant to the AbbVie Development Agreement CollPlant grants AbbVie, its affiliates and third-party transferees a right to use any know-how related to CollPlant rhCollagen that is (a) necessary or useful to exploit an exclusive product and (b) controlled by CollPlant or its affiliates, solely to support the regulatory approval of such exclusive product.

The Company determined that those rights described above are to the use of the IP of CollPlant, therefore represent a right under a license contract. The Company farther identified the license as a performance obligation.

The transaction price included an up-front paid amount of $14,000 as well as variable considerations contingent upon the Company or AbbVie achieving certain milestones and sales-based royalties ("Variable Consideration").

The potential milestones will be included in the transaction price when the Company concludes that achievement of the milestones is probable, and that recognition of revenue related to the milestones will not result in a significant reversal in amounts recognized in future periods, and as such have been excluded from the transaction price until such probability is achieved. Any consideration related to sales-based royalties will be recognized if and when the related sales occur.

In June 2023, the Company received notification from AbbVie about achievement of a milestone with respect to the dermal filler product. According to the AbbVie Development Agreement, the milestone achievement triggered a $10,000 payment from AbbVie to CollPlant. Such payment received in July 2023, and recognized as revenue in the year 2023 (see Note 11).

NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES (continued)

q. Income taxes

1) Deferred taxes

Income taxes are computed using the asset and liability method. Under the asset and liability method, deferred income tax assets and liabilities are determined based on the differences between the financial reporting and tax bases of assets and liabilities and are measured using the currently enacted tax rates and laws. A valuation allowance is recognized to the extent that it is more likely than not that the deferred taxes will not be realized in the foreseeable future.

2) Uncertainty in income taxes

The Company follows a two-step approach in recognizing and measuring uncertain tax positions. The first step is to evaluate the tax position for recognition by determining if the available evidence indicates that it is more likely than not that the position will be sustained based on technical merits. If the more likely than not threshold is met, the second step is to measure the tax position as the largest amount that has more than a 50% likelihood of being realized upon ultimate settlement. When applicable, the Company accounts for interest and penalties related to unrecognized tax benefits as a component of income tax expense. As of December 31, 2024 and 2023, no liability for unrecognized tax benefits was recorded.

r. Income (loss) per share

Basic income (loss) per share is computed on the basis of the net income (loss), for the period divided by the weighted average number of ordinary shares outstanding during the period. Diluted income (loss) per share is based upon the weighted average number of ordinary shares and of ordinary shares equivalents outstanding when dilutive. Ordinary share equivalents include outstanding share options restricted share and warrants, which are included under the treasury stock method when dilutive.

The calculation of diluted loss per share does not include options, restricted share units and warrants exercisable into 2,195,421 , 2,007,546 and 2,558,164 shares for the years ended December 31, 2024, 2023, and 2022, respectively, because the effect would be anti-dilutive.

NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES (continued)

s. Fair value measurement

Fair value is based on the price that would be received from the sale of an asset or that would be paid to transfer a liability in an orderly transaction between market participants at the measurement date. In order to increase consistency and comparability in fair value measurements, the guidance establishes a fair value hierarchy that prioritizes observable and unobservable inputs used to measure fair value into three broad levels, which are described as follows:

Level 1: Quoted prices (unadjusted) in active markets that are accessible at the measurement date for assets or liabilities.

Level 2: Observable prices that are based on inputs not quoted on active markets, but corroborated by market data.

Level 3: Unobservable inputs are used when little or no market data is available.

In determining fair value, the Company utilizes valuation techniques that maximize the use of observable inputs and minimize the use of unobservable inputs to the extent possible and considers counterparty credit risk in its assessment of fair value. A financial instrument's categorization within the valuation hierarchy is based upon the lowest level of input that is significant to the fair value measurement.

The carrying amount of the cash and cash equivalents, restricted deposits, trade receivable, trade payables, accrued expenses and other liabilities approximates their fair value.

t. Warrants:

There were no issued warrants during the twelve months ended December 31, 2024, 2023 and 2022. The Company assessed the warrants pursuant to ASC 480 "Distinguishing Liabilities from Equity" and ASC 815 "Derivatives and Hedging" and determined that the warrants should be accounted for as equity and not as a derivative liability.

u. Severance Pay

All of the Company's employees who are Israeli citizens have subscribed to Section 14 of Israel's Severance Pay Law, 5723-1963 (the "Severance Pay Law"). Pursuant to Section 14 of the Severance Pay Law, employees covered by this section are entitled to monthly deposits at a rate of 8.33% of their monthly salary, made on their behalf by the Company. Payments made to employees in accordance with this section release the Company from any future severance liabilities with respect to such employees. Neither severance pay liability nor severance pay fund under Section 14 of the Severance Pay Law is recorded on the Company's consolidated balance sheets.

(U.S. dollars in thousands, except share and per share data)

NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES (continued)

v. Newly issued and recently adopted accounting pronouncements:

In November 2023, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2023-07, "Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures", which requires public entities to disclose information about their reportable segments' significant expenses and other segment items on an interim and annual basis. Public entities with a single reportable segment are required to apply the disclosure requirements in ASU 2023-07, as well as all existing segment disclosures and reconciliation requirements in ASC 280 on an interim and annual basis. ASU 2023-07 is effective for fiscal years beginning after December 15, 2023, and for interim periods within fiscal years beginning after December 15, 2024, with early adoption permitted. The Company's adoption of this standard as of January 1, 2024. The adoption of this ASU did not have a material significant impact on the Company's consolidated balance sheets, consolidated statements of income (loss), consolidated statements of shareholders' equity or consolidated statements of cash flows.

New accounting pronouncements not yet effective:

In December 2023, the FASB issued ASU 2023-09, Income Taxes (Topic 740): Improvements to Income Tax Disclosures, which requires public entities, on an annual basis, to provide disclosure of specific categories in the rate reconciliation, as well as disclosure of income taxes paid disaggregated by jurisdiction. ASU 2023-09 is effective for fiscal years beginning after December 15, 2024, with early adoption permitted. The Company is currently evaluating the impact of adopting ASU 2023-09.

In November 2024, the FASB issued ASU 2024-03, Income Statement, Reporting Comprehensive Income, Expense Disaggregation Disclosures (Subtopic 220-40). ASU 2024-03 requires that public business entities disclose more detailed information about types of expenses in commonly presented expense captions. This guidance is effective for annual reporting periods beginning after December 31, 2026, and for interim reporting periods beginning after December 15, 2027. The Company is currently evaluating the impact of adopting ASU 2024-03.

NOTE 3 - INVENTORIES, NET

a. Inventories on December 31, 2024 and 2023 consisted of the following:

	December 31,	
	2024	**2023**
Work in progress	$ 286	$ 173
Finished goods	154	541
	$ 440	$ 714

b. The Company recorded inventories write-downs of $286, $866 and $296 for the years ended December 31, 2024, 2023 and 2022, respectively, which were recorded as part of cost of revenues.

(U.S. dollars in thousands, except share and per share data)

NOTE 4 - PROPERTY AND EQUIPMENT, NET

	December 31	
	2024	2023
Cost:		
Laboratory equipment	$ 2,135	$ 1,979
Production equipment	1,885	1,769
Greenhouse equipment	772	771
Computer and electronic equipment	351	306
Office furniture	280	266
Leasehold improvements	3,650	3,503
Vehicles	241	241
	9,314	8,835
Less:		
Accumulated depreciation	(7,024)	(6,046)
Property and Equipment, net	$ 2,290	$ 2,789

Depreciation expenses totaled $981, $1,045 and $1,036 for the years ended December 31, 2024, 2023 and 2022, respectively.

During the year ended December 31, 2024, 2023 and 2022, the Company disposed of property and equipment in the net amount of $1, $86 and $7, respectively.

(U.S. dollars in thousands, except share and per share data)

NOTE 5 - LEASES

The Company's leases includes the production sites, corporate headquarter, research lab center and car leases, which are all classified as operating leases. The car leases are generally for three years period and the payments are linked to the Israeli CPI. The Company's ROU assets and lease liabilities were calculated using the initial CPI and will not be subsequently adjusted.

As collateral for part of the lease agreements, a restricted deposit was pledged in favor of the property owners. The balance of the restricted deposit as of December 31, 2024 amounted to $195, classified as current assets, and $118 classified as non-current asset.

To secure the terms of the car lease agreements, the Company has made certain prepayments to the leasing company, representing approximately three months of lease payments.

Operating leases cost for space and cars for the years ended December 31, 2024, 2023 and 2022 totaled $881, $775, and $645, respectively.

The operating lease costs include variable lease payments of $77, $52, and $24 in 2024, 2023 and 2022, respectively.

Supplemental cash flow information related to leases was as follows:

	Year ended December 31,	
	2024	2023
Operating cash flows from operating leases	$ 941	$ 809

Supplemental balance sheet information related to leases was as follows:

	December 31,	
	2024	2023
Operating Leases		
Operating lease right-of-use assets	$ 2,991	$ 3,070
Current lease liabilities	$ 806	$ 624
Non-current lease liabilities	2,275	2,535
Total lease liabilities	$ 3,081	$ 3,159
Weighted Average Remaining Lease Term		
Operating leases	4.25 years	5.14 years
Weighted Average Discount Rate		
Operating leases	7.77%	7.46%

(U.S. dollars in thousands, except share and per share data)

NOTE 5 - LEASES (continued)

As of December 31, 2024, the maturities of lease liabilities were as follows:

	Operating leases
Year ending December 31,	
2025	$ 926
2026	831
2027	776
2028	765
2029	325
Thereafter	-
Total undiscounted lease payments	3,623
Less – imputed interests	(542)
Present value of lease liabilities	$ 3,081

NOTE 6 - COMMITMENTS AND CONTINGENCIES

a. Commitment to pay royalties to the government of Israel

The Company received grants from the IIA for research and development funding until the year 2019, and therefore is subject to the provisions of the Israeli Law for the Encouragement of Research, Development and Technological Innovation in the Industry and the regulations and guidelines thereunder (the "Innovation Law"), the regulations promulgated thereunder, the IIA's rules and guidelines and the terms of the approved program funded by the IIA. Under the Innovation Law royalties of 3% on the income deriving from products and from related know-how and services developed in whole or in part, directly or indirectly, under IIA programs are payable to the IIA. Such commitment is up to the amount of grants received (dollar linked), plus interest at annual rate based on SOFR. In addition to paying any royalty due, the Company must abide by other restrictions associated with receiving such grants under the Innovation Law that continue to apply following repayment to the IIA. These restrictions may impair the Company's ability to outsource manufacturing or otherwise transfer its know-how outside of Israel and may require it to obtain the approval of the IIA for certain actions and transactions and pay additional royalties and other amounts to the IIA.

The Company did not apply for grants from the IIA since 2019. For the years ended December 31, 2024, 2023 and 2022, the Company recorded royalties expenses of $15, $329 and $9, respectively.

The royalty expenses which are related to the funded project are recognized in the statements of operations as a component of cost of revenue.

As of December 31, 2024, the maximum total royalty amount payable by the Company under IIA funding arrangement is approximately $6,966 (without interest).

NOTE 6 - COMMITMENTS AND CONTINGENCIES (continued)

b. Contingent liability

As of December 31, 2024, the Company has a contingent liability related to annual cash incentives, accumulating to a potential liability of approximately $453.

NOTE 7 - DEVELOPMENT, EXCLUSIVITY AND OPTION PRODUCTS AGREEMENTS

On February 5, 2021, CollPlant entered into development and global commercialization agreement (the "AbbVie Development Agreement") with Allergan, an AbbVie company, pursuant to which CollPlant and AbbVie agreed to collaborate in the development and commercialization of dermal and soft tissue filler products for the medical aesthetics market, using CollPlant rhCollagen technology and AbbVie's technology.

Pursuant to the AbbVie Development Agreement, CollPlant agreed to undertake projects for the development of an aseptic process for sterile rhCollagen that meets or exceeds certain specifications as set forth in the Development Agreement.

Pursuant to the AbbVie Development Agreement, CollPlant granted to AbbVie and its affiliates, worldwide exclusive rights to use its rhCollagen in combination with AbbVie proprietary technologies, for the production and commercialization of dermal and soft tissue filler products, or the Exclusive Products. Further, pursuant to the AbbVie Development Agreement, CollPlant granted to AbbVie and its affiliates, a right of first negotiation to enter into a definitive agreement to obtain exclusive, worldwide rights to the use of CollPlant rhCollagen for the commercialization and sale of an injectable breast implant product and a right of first negotiation to enter into a definitive agreement to obtain exclusive, worldwide rights to the use of CollPlant's rhCollagen for the commercialization and sale of a photocurable dermal filler product, each an "Option Product" and together, the "Option Products". Other than under the AbbVie Development Agreement, CollPlant agreed not to research, develop or commercialize its rhCollagen for use with any Exclusive Products during the term of the Development Agreement or grant any third party any rights to CollPlant's rhCollagen technology that would conflict with rights granted to AbbVie.

The AbbVie Development Agreement provides that later on CollPlant and AbbVie will enter into a supply agreement whereby CollPlant will manufacture and supply AbbVie with rhCollagen, at a pre-agreed price, to be used solely for the development and manufacture of the Exclusive Products and Option Products.

The AbbVie Development Agreement provides that with respect to the Exclusive Products CollPlant shall be entitled to receive up to $50,000 comprised of an upfront cash payment of $14,000, which was paid in February 2021, and up to $36,000 in proceeds upon the achievement of certain development, clinical trial, regulatory and commercial sale milestones. In June 2023, a milestone under the AbbVie Development Agreement was achieved. Such milestone achievement triggered a payment of $10,000 from AbbVie to CollPlant, which was received in July 2023. In addition, CollPlant shall be entitled to a fixed-fee royalty payment (subject to certain adjustments) for each product commercially sold during the applicable royalty term as well as a fee for the supply of rhCollagen to AbbVie. In addition, with respect to the Option Products, CollPlant shall be entitled to receive up to $53,000, as further described below, plus a fixed-fee royalty payment (subject to certain adjustments) for each product commercially sold during the applicable royalty term and a fee for the supply of rhCollagen to AbbVie.

NOTE 7 - DEVELOPMENT, EXCLUSIVITY AND OPTION PRODUCTS AGREEMENTS (continued)

The $53,000 in proceeds includes a one-time non-refundable payment of $6,000 upon signing a definitive agreement with regards to the injectable breast implant product; a one-time non-refundable payment of $4,000 for signing a definitive agreement with regards to the photocurable dermal filler product; and up to an additional $43,000 payable upon the achievement of certain clinical trial, regulatory approval and commercial sale milestones (see Note 11).

Unless earlier terminated, the AbbVie Development Agreement will continue in effect on a product-by-product and country-by-country basis until the later of (i) the expiration, invalidation or abandonment of the last CollPlant patent covering a product in a particular country, and (ii) 10 years from the first commercial sale of such product in such country. Following expiration (unless earlier terminated), the rights granted to AbbVie in the AbbVie Development Agreement will continue on a non-exclusive, fully paid-up, royalty-free, perpetual and irrevocable basis. The AbbVie Development Agreement may be terminated early by either party for material breach or bankruptcy. In addition, AbbVie may terminate the AbbVie Development Agreement at any time immediately upon written notice to CollPlant if AbbVie reasonably believes that it is not advisable for AbbVie to continue to develop or commercialize the Exclusive Products under the AbbVie Development Agreement as a result of a perceived serious safety issue regarding the use of any Exclusive Product or upon 60 days' written notice, for any or no reason, with respect to its rights under the AbbVie Development Agreement on an Exclusive Product-by-Exclusive Product or country-by-country basis.

NOTE 8 - SHARE CAPITAL

A. Ordinary shares

1) **Rights of the Company's ordinary shares**

Each ordinary share is entitled to one vote. The holder of the ordinary shares is also entitled to receive dividends whenever funds are legally available, when and if declared by the Board of Directors. Since its inception, the Company has not declared any dividends.

2) **Changes in share capital:**

In 2022, three U.S investors exercised 425,000 warrants into 425,000 ordinary shares in return of $1,700.

In 2023, Mr. Sagy exercised 186,000 warrants into 186,000 ordinary shares in return of $744.

(U.S. dollars in thousands, except share and per share data)

NOTE 8 - SHARE CAPITAL (continued)

B. Share-based compensation:

1) **Option plan**

Under the Company's Share Ownership and Option Plan (2010), or the 2010 Plan, employees, directors and consultants of the Company may be granted options, each exercisable into one ordinary share of the Company of NIS 1.50 par value.

On April 3, 2024, the board of directors approved the adoption of a share award plan (the "2024 Plan"). The 2024 Plan allows the Company to grant its employees, directors and consultants with several equity-based awards, including options, shares, restricted shares, restricted share units, stock appreciation rights, performance units, performance shares and other stock or cash awards. The 2024 Plan shall be in effect for a term of ten (10) years from the date of adoption, i.e., until April 2034, unless earlier terminated by its administrator.

2) **Options grants**

a. Option granted to employees, directors and consultants

In the years ended December 31, 2024, 2023 and 2022, the Company granted options as follows (amounts presented reflect the number of shares underlying options):

	Year ended December 31, 2024			
	Award amount	**Exercise price range**	**Vesting period**	**Expiration**
Employees	50,500	$ 4.26-5.76	4 years	10 years
Consultants	25,000	$ 5.26	4 years	10 years

	Year ended December 31, 2023			
	Award amount	**Exercise price range**	**Vesting period**	**Expiration**
Employees	158,000	$ 5.65-7.5	4 years	10 years

(U.S. dollars in thousands, except share and per share data)

NOTE 8 - SHARE CAPITAL (continued)

	Year ended December 31, 2022			
	Award amount	Exercise price range	Vesting period	Expiration
Employees	529,000	$ 5.33-9.22	4 years	10 years
Directors	217,000	$ 9.22	4 years	10 years

The fair value of options granted on the date of grant was computed using the Black-Scholes model. The underlying data used for computing the fair value of the options are as follows:

	Year ended December 31,		
	2024	2023	2022
Value of one ordinary share	$ 4.27-5.46	$ 5.73-7.5	$ 5.03-9.22
Dividend yield	0%	0%	0%
Expected volatility	70.91-71.14%	70.27-74.1%	67.95-72.27%
Risk-free interest rate	4.21-4.46%	3.62-4.33%	0.39-3.03%
Expected term	6.11 years	6.11 years	6.11 years

A summary of options data for the years ended December 31, 2024, 2023 and 2022, is as follows:

	Year ended December 31,		
	2024	2023	2022
Total fair value of options granted	$ 252	$ 747	$ 3,970
Weighted-average grant date fair value of options granted, per option	$ 3.33	$ 4.73	$ 5.32
Total intrinsic value of the options exercised	$ *	$ 271	$ 221
Total fair value of options vested	$ 1,549	$ 4,380	$ 2,802

* Less than 1

(U.S. dollars in thousands, except share and per share data)

NOTE 8 - SHARE CAPITAL (continued)

The following table summarizes the activity in options granted to employees and directors for the year ended December 31, 2024:

	2024			
	Number of options	Weighted average exercise price*	weighted average remaining contractual term (in years)	aggregate intrinsic value*
Options outstanding at the beginning of the year	1,745,880	$ 5.80	5.91	$ 1,165
Granted	50,500	5.15	8.57	-
Exercised	(1,840)	5.07	-	-
Expired	(29,313)	6.99	-	-
Forfeited	(37,472)	6.22	-	-
Options outstanding at the end of the year	1,727,755	$ 5.75	4.99	$ -
Options exercisable at the end of the year	1,383,902	$ 5.64	4.27	$ -

* After repricing- see Note 8(B)(2)(a).

The following table summarizes the activity in options granted to consultants for the year ended December 31, 2024:

	2024			
	Number of options	Weighted average exercise price	weighted average remaining contractual term (in years)	aggregate intrinsic value
Options outstanding at the beginning of the year	11,666	$ 16.78	1.36	$ 2
Granted	25,000	4.46	9.78	-
Options outstanding at the end of the year	36,666	$ 8.35	6.78	$ -
Options exercisable at the end of the year	6,329	$ 9.95	0.34	$ -

NOTE 8 - SHARE CAPITAL (continued)

Modification of share-based compensation

1. On April 3, 2024, the board of directors (following the approval of the compensation committee with respect to the Company's directors and officers) approved to extend the expiry date of 337,464 options exercisable into 337,464 ordinary shares that were previously granted to some of the Company's employees and directors, from an expiry date ranging between December 2024 and July 2025, by an additional three years, such that the expiry dates will range between December 2027 and July 2028. Out of the said options, 126,800 options exercisable into 126,800 ordinary shares are held by some of the Company's directors and its CEO (who also serves as a director on the board of directors), and as such, the extension of the expiry dates of these options is subject to the approval of the general meeting of the shareholders, which approval was obtained on September 25, 2024.

   The total incremental fair value of these options granted to the Company's employees and directors amounted to $314 and was determined based on the Black-Scholes pricing options model using the following assumptions: risk free interest rate of 3.53%-4.68%, expected volatility of 53.4% - 71.62%, expected term of 1.65-2.16 years and dividend yield of 0%. For the year ended December 31, 2024, the Company recorded the total expenses from these extended options in amount of $314.

2. On August 23, 2023, the Company's board of directors approved the repricing of the exercise price of outstanding options to purchase 969,886 ordinary shares, previously granted to employees and directors, to a price of $6.39 per share, out of which the repricing of 583,979 options granted to the Company's directors and the Chief Executive Officer, were subject to the approval of the general meeting of the shareholders, which approval was obtained on October 10, 2023. There was no change in the number of shares subject to each option, vesting or other terms of the options.

   The total incremental fair value of these options amounted to $579 and was determined based on the Black-Scholes pricing options model using the following assumptions: risk free interest rate of 4.33%-4.74%, expected volatility of 72.1% - 77%, expected term of 3.4-4.71 years and dividend yield of 0%. For the year ended December 31, 2024 and 2023, the Company recorded expenses totaling $35 and $523 associated with the repricing. The remaining incremental fair value will be recognized over the remaining vesting period and until May 2026.

(U.S. dollars in thousands, except share and per share data)

NOTE 8 - SHARE CAPITAL (continued)

The following tables summarize information concerning outstanding and exercisable options as of December 31, 2024:

	December 31, 2024				
	Options outstanding			Options exercisable	
Exercise prices *	Number of options outstanding at end of year	Weighted average remaining contractual Life		Number of options exercisable at end of year	Weighted average remaining contractual life
$ 24.68	6,666	0.38		1,329	0.38
7.50	98,562	8.24		43,436	8.24
6.50	15,500	8.65		5,531	8.65
6.39	948,572	6.33		780,313	6.13
6.03	5,000	0.33		5,000	0.33
5.76	5,000	9.44		-	-
5.65	17,000	8.92		4,250	8.92
5.33	104,157	7.92		52,408	7.92
5.26	37,000	9.26		-	-
5.07	145,500	1.08		145,500	1.08
$ 4.26	29,000	9.91		-	-
4.02	352,464	0.29		352,464	0.29
	1,764,421			1,390,231	

* In U.S. dollars per Ordinary Share.

b) **RSU grants**

In the year ended December 31, 2024, the Company granted restricted share units, or RSU, as follows:

	Year ended December 31, 2024	
	Number of RSU granted	Weighted Average Grant Date Fair Value
Employees	341,000	$ 5.05
Directors	100,000	$ 4.78

(U.S. dollars in thousands, except share and per share data)

NOTE 8 - SHARE CAPITAL (continued)

The following table summarizes the activity in RSU granted to employees and directors under the 2024 Plan for the year ended December 31, 2024:

	Number of options	Weighed Average Grant Date Fair Value
Unvested at the beginning of the period	-	$ -
Granted	441,000	4.99
Unvested at the end of the period	441,000	$ 4.99

c. The following table illustrates the effect of share-based compensation on the statements of operations:

	Year ended December 31		
	2024	2023	2022
Cost of revenues	$ -	$ -	$ 22
Research and development expenses	783	714	565
General, administrative and marketing expenses	936	1,223	1,587
	$ 1,719	$ 1,937	$ 2,174

As of December 31, 2024, there was $2,165 of unrecognized compensation expense related to unvested RSUs and options. This amount is expected to be recognized over a weighted-average period of 1.82 years.

(U.S. dollars in thousands, except share and per share data)

NOTE 9 - INCOME TAX

The Company and its Israeli subsidiary are taxed under Israel tax laws:

A. Tax rates

After the Company consummates its Net Operating Losses, the corporate tax rate applicable for the years 2022-2024, is 23%.

B. Tax assessments

The Company and its subsidiary have tax assessments that are considered to be final through tax year 2019.

C. Losses for tax purposes carried forward to future years

As of December 31, 2024, CollPlant Biotechnologies Ltd. and CollPlant Ltd had approximately $35,242, and $45,991, respectively, of net carried forward tax losses which are available to be offset against future taxable income in future with no limited period of use.

D. Deferred income taxes

	2024	2023
Deferred tax assets		
Net operating loss carry forward	$ 18,684	$ 15,492
Research and development expenses	2,034	1,993
Operating lease liabilities	709	726
Share-based compensation	2,028	1,762
Total gross deferred tax assets	23,455	19,973
Less – valuation allowance	(22,767)	(19,267)
Deferred tax liabilities:		
Operating lease assets	688	706
Net deferred tax assets	$ -	$ -

Realization of deferred tax assets is contingent upon sufficient future taxable income during the period that deductible temporary differences and carried forward losses are expected to be available to be offset against taxable income. As the achievement of required future taxable income is not likely, the Company recorded a full valuation allowance.

E. Reconciliation of theoretical tax expenses to actual expenses

The primary difference between the statutory tax rate of the Company and the effective rate results virtually from the changes in valuation allowance in respect of carried forward tax losses for tax purposes and research and development expenses due to the uncertainty of the realization of such tax benefits.

(U.S. dollars in thousands, except share and per share data)

NOTE 9 - INCOME TAX (continued)

F. Uncertain tax positions

As of December 31, 2024 and 2023, the Company does not have a provision for uncertain tax positions.

G. Roll forward of valuation allowance:

Balance at December 31, 2023	$ (19,267)
Change	(3,500)
Balance at December 31, 2024	$ (22,767)

NOTE 10 - SUPPLEMENTARY FINANCIAL STATEMENT INFORMATION:

Balance sheets:

	December 31,	
	2024	**2023**
a. Accrued liabilities and other payables:		
Employees and institutions for employees	$ 656	$ 1,052
Provisions for vacation	537	490
Royalties and Other	101	105
	$ 1,294	$ 1,647

Statements of operations:

b. Revenues

1) **Disaggregated revenues**

	Year ended December 31,		
	2024	**2023**	**2022**
Revenues from licensing agreement (see Note 2(p))	$ -	$ 10,000	$ -
Revenues from the sales of goods	515	959	299
Total revenues	$ 515	$ 10,959	$ 299

(U.S. dollars in thousands, except share and per share data)

NOTE 10 - SUPPLEMENTARY FINANCIAL STATEMENT INFORMATION (continued)

2) **Revenues by geographical area (based on the location of customers):**

	Year ended December 31,		
	2024	**2023**	**2022**
United states	$ 484	$ 10,839	$ 16
Canada	-	87	158
Europe and Other	-	28	104
Israel	31	5	21
Total revenues	$ 515	$ 10,959	$ 299

3) **Major customers**

Set forth below is a breakdown of the Company's revenue by major customers (major customer –revenues from these customers constitute at least 10% of total revenues in a certain year):

	Year ended December 31,		
	2024	**2023**	**2022**
Customer A	$ 476	$ 10,743	$ 9
Customer B	$ -	$ -	101
Customer C	$ -	$ 79	158

4) **The changes in deferred revenues relating to goods that were not yet delivered are as follows:**

	2022
Balance at beginning of year	$ (32)
Contract liability recognized during the period	-
Revenue recognized during the period	32
Balance at end of year	$ -
Contract liability presented in current liabilities	$ -
Contract liability presented in non-current liabilities	$ -

There were no deferred revenues balances for 2024 and 2023.

(U.S. dollars in thousands, except share and per share data)

NOTE 10 - SUPPLEMENTARY FINANCIAL STATEMENT INFORMATION (continued)

c. Long-lived assets

All of the Company's operating Right-of-use lease assets and long-lived assets are located in Israel.

d. Financial income (expenses), net

	Year ended December 31,		
	2024	**2023**	**2022**
Exchange rate differences	$ (79)	$ (285)	$ (115)
Bank and other fees	(17)	(10)	(10)
Other financing expenses	-	-	(24)
Interest on bank deposits	738	788	321
Financial income, net	$ 642	$ 493	$ 172

NOTE 11 - SUBSEQUENT EVENTS

In January 2025, the Company received a contingent payment with respect to CollPlant's rhCollagen, which, according to the AbbVie Development Agreement, triggers a $2,000 payment from AbbVie to CollPlant. The payment received and recognized as revenue in the first quarter of 2025.

Exhibit 2.1

DESCRIPTION OF SECURITIES

REGISTERED UNDER SECTION 12 OF THE EXCHANGE ACT

General

The authorized and registered share capital of CollPlant Biotechnologies Ltd. (the "Company") is NIS 45,000,000 divided into 30,000,000 ordinary shares, nominal (par) value NIS 1.50 each.

The Nasdaq Global Market

Our ordinary shares are listed on The Nasdaq Capital Market under the symbol "CLGN".

Memorandum and Articles of Association

Articles of Association

The following are summaries of material provisions of our articles of association and the Companies Law insofar as they relate to the material terms of our ordinary shares.

Purposes and Objects of the Company

Our purpose as set forth in our articles of association is to engage in any lawful activity.

Registration Number

Our registration number with the Israeli Registrar of Companies is 52-0039785.

Voting Rights and Conversion

All ordinary shares have identical voting and other rights in all respects.

Transfer of Shares

Our fully paid ordinary shares are issued in registered form and may be freely transferred under our articles of association, unless the transfer is restricted or prohibited by another instrument, applicable law, or the rules of a stock exchange on which the shares are listed for trade. The ownership or voting of our ordinary shares by non-residents of Israel is not restricted in any way by our articles of association or the laws of the State of Israel, except for ownership by nationals of some countries that are, or have been, in a state of war with Israel.

Election of Directors

Our ordinary shares do not have cumulative voting rights for the election of directors. As a result, the holders of a majority of the voting power represented at a shareholders meeting have the power to elect all of our directors, subject to the special approval requirements for external directors.

Under our Articles, our board of directors must consist of not less than three but no more than twelve directors, which includes two external directors, as may be required under the Companies Law. Pursuant to our Articles, other than the external directors, for whom special election requirements apply under the Companies Law, the vote required to appoint a director is a simple majority vote of holders of our voting shares, participating and voting at the relevant meeting. Each director will serve until his or her successor is duly elected and qualified or until his or her earlier death, resignation, or removal by a vote of the majority voting power of our shareholders at a general meeting of our shareholders or until his or her office expires by operation of law, in accordance with the Companies Law. In addition, our Articles allow our board of directors to appoint, with immediate effect or for a future date, additional director(s) who will serve until the Company's next annual general meeting, provided that the total number of directors that shall serve will not exceed the maximum number of directors permitted under our Articles.

Dividend and Liquidation Rights

We may declare a dividend to be paid to the holders of our ordinary shares in proportion to their respective shareholdings. Under the Companies Law, dividend distributions are determined by the board of directors and do not require the approval of the shareholders of a company unless the company's articles of association provide otherwise. Our articles of association do not require shareholder approval of a dividend distribution and provide that dividend distributions may be determined by our board of directors.

Pursuant to the Companies Law, the distribution amount is limited to the greater of retained earnings or earnings generated over the two most recent fiscal years, according to our then last reviewed or audited financial statements, provided that the date of the financial statements is not more than six months prior to the date of the distribution, or we may otherwise only distribute dividends that do not meet such criteria only with court approval. In each case, we are only permitted to distribute a dividend if our board of directors or the court, if applicable, determines that there is no reasonable concern that payment of the dividend will prevent us from satisfying our existing and foreseeable obligations as they become due, which is referred to as the Solvency Test. Pursuant to regulations promulgated under the Companies Law, Israeli companies listed on certain non-Israeli stock exchanges, including the Nasdaq, may distribute a dividend by way of a share repurchase program (buy-back) if the company does not meet the profit test, without seeking the approval of the court, subject to the following conditions: (i) the company meets the Solvency Test; and (ii) the company provides a notice to certain creditors of its intention to distribute a dividend by way of a share repurchase program without meeting the profit test and no such creditor submits an objection within 30 days of the notice (otherwise, court approval would be required for such distribution in accordance with the requirements of the Israeli Companies Law).

In the event of our liquidation, after satisfaction of liabilities to creditors, our assets will be distributed to the holders of our ordinary shares in proportion to their shareholdings. This right, as well as the right to receive dividends, may be affected by the grant of preferential dividend or distribution rights to the holders of a class of shares with preferential rights that may be authorized in the future.

Shareholder Meetings

Under Israeli law, we are required to hold an annual general meeting of our shareholders once every calendar year that must be held no later than 15 months after the date of the previous annual general meeting. All meetings other than the annual general meeting of shareholders are referred to in our articles of association as extraordinary general meetings. Our board of directors may call extraordinary general meetings whenever it sees fit, at such time and place, within or outside of Israel, as it may determine.

In addition, the Companies Law and the regulations promulgated thereunder provide a relief to companies listed on certain non-Israeli stock exchanges, such as ourselves, under which the board of directors is required to convene an extraordinary general meeting upon the written request of (i) any two of our directors or one-quarter of the members of our board of directors or (ii) one or more shareholders holding, in the aggregate, either (a) 10% or more of our outstanding issued shares and 1% of our outstanding voting power or (b) 10% or more of our outstanding voting power (instead of a 5% threshold set under the Companies Law with respect to public companies whose shares are traded on the Tel Aviv Stock Exchange alone). Such relief does not apply if the law of the foreign country in which such company's shares are traded establishes a right to demand the convening of a meeting for those who hold a percentage of less than 10%. Nonetheless, our articles of association adopt the provisions of the Companies Law that apply to public companies whose shares are traded on the Tel Aviv Stock Exchange, as aforementioned.

Subject to the provisions of the Companies Law and the regulations promulgated thereunder, shareholders entitled to participate and vote at general meetings are the shareholders of record on a date to be decided by the board of directors, which may be between four and 40 days prior to the date of the meeting (and, with respect to companies listed on certain non-Israeli stock exchanges, including the Nasdaq, such as ourselves, up to 60 days prior to the date of the meeting). Furthermore, the Companies Law requires that resolutions regarding the following matters must be passed at a general meeting of our shareholders:

- amendments to our articles of association;
- appointment or termination of our auditors;
- appointment of external directors;
- approval of certain related party transactions;
- increases or reductions of our authorized share capital;
- a merger; and
- the exercise of our board of director's powers by a general meeting, if our board of directors is unable to exercise its powers and the exercise of any of its powers is required for our proper management.

The Companies Law and the regulations thereof require that a notice of any annual general meeting or extraordinary general meeting be provided to shareholders at least 21 days or 14 days, as applicable, prior to the meeting and if the agenda of the meeting includes, for example, the appointment or removal of directors, the approval of transactions with office holders or interested or related parties, or an approval of a merger, notice must be provided at least 35 days prior to the meeting.

One or more shareholders holding at least 1% of the voting rights in the general meeting are entitled to request the company's board of directors to include a proposal on the agenda of a general meeting, provided that the proposal is appropriate to be discussed at a general meeting. Regulations promulgated under the Companies Law provide that such a request should be provided between three to seven days following the notice on the convening of the general meeting, depending on the items on the agenda of such meeting. Pursuant to regulations promulgated under the Israeli Companies Law which apply to companies listed on certain non-Israeli stock exchanges, such as ourselves, a shareholder who wishes to add an item to the agenda of a general meeting which entails the proposal of a candidate to serve as a director on the board of directors, may do so if such shareholders holds 5% or more of our voting rights (instead of 1%).

All shareholder decisions are to be taken by votes in a shareholders' meeting. Under the Companies Law and our articles of association, shareholders are not permitted to take action via written consent in lieu of a meeting.

Voting Rights

Quorum Requirements

Pursuant to our articles of association, holders of our ordinary shares have one vote for each ordinary share held on all matters submitted to a vote before the shareholders at a general meeting. As a foreign private issuer, the quorum required for our general meetings of shareholders consists of at least two shareholders present in person, by proxy, or written ballot who hold or represent between them at least 20% of the total outstanding voting rights. A meeting adjourned for lack of a quorum is generally adjourned to the same day in the following week at the same time and place or to a later time or date if so specified in the notice of the meeting. At the reconvened meeting, any two or more shareholders present in person or by proxy shall constitute a lawful quorum.

Vote Requirements

Our Articles provide that all resolutions of our shareholders require a simple majority vote, unless otherwise required by the Companies Law or by our Articles. Under the Companies Law, the primary types of engagements or transactions that require approval of our shareholders by a special majority include the following: (i) the approval of an extraordinary transaction with a controlling shareholder or the approval of the terms of employment or other engagement of a controlling shareholder of the company or such controlling shareholder's relative (even if not extraordinary), each of which requires the approval described under "Directors, Senior Management and Employees—Board Practices—Approval of Related Party Transactions Under Israeli Law—Disclosure of Personal Interests of Controlling Shareholders and Approval of Certain Transactions" in our most recent Annual Report on Form 20-F; (ii) the approval of our compensation policy for directors and officers, or the approval of compensation terms to a director or officer which deviate from the terms of the compensation policy, which requires the approval described under "Directors, Senior Management and Employees—Board Practices—Committees of the Board of Directors—Compensation Committee", which we refer to as the Special Majority for Compensation; (iii) the approval of the terms of employment of our CEO, which requires the approval of our shareholders by a Special Majority for Compensation; and (iv) the appointment of our external directors, to the extent that such external directors shall serve on our board of directors, which requires the approval of a majority vote of the shares present and voting at a meeting of shareholders, provided that either: (a) such majority includes at least a majority of the shares held by all shareholders who are not controlling shareholders of the company or have a personal interest in the approval of the item, other than a personal interest that is not as a result of relations with the controlling shareholder participating in the voting; or (b) the total number of shares out of the shareholders detailed in section (a) who vote against the arrangement does not exceed 2% of the company's aggregate voting rights.

Access to Corporate Records

Under the Companies Law, shareholders are provided access to: minutes of our general meetings; our shareholders register and principal shareholders register, articles of association and financial statements; and any document that we are required by law to file publicly with the Israeli Companies Registrar. In addition, shareholders may request to be provided with any document related to an action or transaction requiring shareholder approval under the related party transaction provisions of the Companies Law. We may deny this request if we believe it has not been made in good faith or if such denial is necessary to protect our interest or protect a trade secret or patent.

Modification of Class Rights

Under the Companies Law and our articles of association, the rights attached to any class of share, such as voting, liquidation, and dividend rights, may be amended by adoption of a resolution by the holders of a majority of the shares of that class present at a separate class meeting, or otherwise in accordance with the rights attached to such class of shares, as set forth in our articles of association.

Registration Rights

Concurrently with the execution of the convertible loan agreements entered into in 2019 with Ami Sagy and certain U.S. Investors, or the 2019 Financing, we entered into Registration Rights Agreements with each of Ami Sagi and the U.S. Investors. Pursuant to the Registration Rights Agreements, we granted one demand registration right to each of Mr. Sagi and the U.S. Investors, which expired in October 2021. In addition, we granted to each of Mr. Sagi and the U.S. Investors F-3 shelf registration rights pursuant to which Mr. Sagi and the U.S. Investors can demand the filing of a shelf registration statement or a public offering under such shelf registration statement, but not more than twice during any 12-month period. We also granted to Mr. Sagi and the U.S. Investors certain piggyback registration rights. All registration rights granted relate to ordinary shares held by Mr. Sagi and the U.S. Investors as well as the ordinary shares to be issued upon exercise of any warrants issued to Mr. Sagi and the U.S. Investors in the 2019 Financing.

As part of the Registration Rights Agreements, we granted customary indemnification rights pursuant to which we undertook to indemnify Mr. Sagi and the U.S. Investors, as the case may be, from and against all Losses (as such term is defined in the Registration Rights Agreements) arising out of or relating to any untrue or alleged untrue statement or omission or alleged omission of a material fact contained in a registration statement and violations of securities laws in connection with the Registration Rights Agreements. Moreover, Mr. Sagi and the U.S. Investors undertook to indemnify us, severally and not jointly, from and against all Losses arising out of or relating to any untrue or alleged untrue statement of a material fact or omission or alleged omission of a material fact contained in any registration statement, but only to the extent that such untrue statement or omission is contained in any information furnished in writing by Mr. Sagi or the U.S. Investors, as the case may be.

We further undertook to bear all fees and expenses incident to the performance of or compliance with the Registration Rights Agreements, whether or not any registerable securities are sold pursuant to a registration statement. This will include all registration and filing fees, printing expenses, communication and delivery expenses, fees and disbursements of counsel for the Company, Securities Act liability insurance (should we desire such insurance), and the fees and expenses of all other persons retained by us in connection with the consummation of the Registration Rights Agreements.

Acquisitions under Israeli Law

Full Tender Offer

A person wishing to acquire shares of an Israeli public company and who would as a result hold over 90% of the target company's issued and outstanding share capital is required by the Companies Law to make a tender offer to all of the company's shareholders for the purchase of all of the issued and outstanding shares of the company. A person wishing to acquire shares of a public Israeli company and who would, as a result, hold over 90% of the issued and outstanding share capital of a certain class of shares is required to make a tender offer to all of the shareholders who hold shares of the relevant class for the purchase of all of the issued and outstanding shares of that class. If the shareholders who do not accept the offer hold less than 5% of the issued and outstanding share capital of the company or of the applicable class, and more than half of the shareholders who do not have a personal interest in the offer accept the offer, all of the shares that the acquirer offered to purchase will be transferred to the acquirer by operation of law. However, a tender offer will also be accepted if the shareholders who do not accept the offer hold less than 2% of the issued and outstanding share capital of the company or of the applicable class of shares.

Upon a successful completion of such a full tender offer, any shareholder that was an offeree in such tender offer, whether such shareholder accepted the tender offer or not, may, within six months from the date of acceptance of the tender offer, petition an Israeli court to determine whether the tender offer was for less than fair value and that the fair value should be paid as determined by the court. However, under certain conditions, the offeror may include in the terms of the tender offer that an offeree who accepted the offer will not be entitled to petition the Israeli court as described above.

If (i) the shareholders who did not respond or accept the tender offer hold at least 5% of the issued and outstanding share capital of the company or of the applicable class or the shareholders who accept the offer constitute less than a majority of the offerees that do not have a personal interest in the acceptance of the tender offer, or (ii) the shareholders who did not accept the tender offer hold 2% or more of the issued and outstanding share capital of the company (or of the applicable class), the acquirer may not acquire shares of the company that will increase its holdings to more than 90% of the company's issued and outstanding share capital or of the applicable class from shareholders who accepted the tender offer.

Special Tender Offer

The Companies Law provides that an acquisition of shares of an Israeli public company must be made by means of a special tender offer if as a result of the acquisition the purchaser would become a holder of 25% or more of the voting rights in the company. This requirement does not apply if there is already another holder of at least 25% of the voting rights in the company. Similarly, the Companies Law provides that an acquisition of shares in a public company must be made by means of a special tender offer if, as a result of the acquisition, the purchaser would become a holder of more than 45% of the voting rights in the company, provided that there is no other shareholder of the company who holds more than 45% of the voting rights in the company, subject to certain exceptions.

A special tender offer must be extended to all shareholders of a company but the offeror is not required to purchase shares representing more than 5% of the voting power attached to the company's outstanding shares, regardless of how many shares are tendered by shareholders. A special tender offer may be consummated only if (i) outstanding shares representing at least 5% of the voting power of the company will be acquired by the offeror and (ii) the number of shares tendered in the offer exceeds the number of shares whose holders objected to the offer (excluding the purchaser, controlling shareholders, holders of 25% or more of the voting rights in the company or any person having a personal interest in the acceptance of the tender offer). If a special tender offer is accepted, then the purchaser or any person or entity controlling it or under common control with the purchaser or such controlling person or entity may not make a subsequent tender offer for the purchase of shares of the target company and may not enter into a merger with the target company for a period of one year from the date of the offer, unless the purchaser or such person or entity undertook to effect such an offer or merger in the initial special tender offer.

Under the Companies Regulations (Relief for Public Companies whose Shared are Traded on Exchanges outside of Israel), the above requirements for a special tender offer do not apply in instances whereby according to the laws of the foreign jurisdiction there are limitations regarding the acquisition of a controlling interest in the company of any specified portion or the acquisition of a controlling interest of any specified portion necessitates an offer by the potential acquirer of a controlling interest to acquire shares from amongst the publicly traded shares.

Merger

The Companies Law permits merger transactions if approved by each party's board of directors and, unless certain requirements described under the Companies Law are met, by a majority vote of each party's shareholders, and, in the case of the target company, a majority vote of each class of its shares voted on the proposed merger at a shareholders meeting.

The board of directors of a merging company is required pursuant to the Companies Law to discuss and determine whether, in its opinion, there exists a reasonable concern that, as a result of a proposed merger, the surviving company will not be able to satisfy its obligations towards its creditors, taking into account the financial condition of the merging companies. If the board of directors has determined that such a concern exists, it may not approve a proposed merger. Following the approval of the board of directors of each of the merging companies, the boards of directors must jointly prepare a merger proposal for submission to the Israeli Registrar of Companies.

For purposes of the shareholder vote, unless a court rules otherwise, the merger will not be deemed approved if a majority of the votes of shares represented at the shareholders meeting that are held by parties other than the other party to the merger, or by any person (or group of persons acting in concert) who holds (or hold, as the case may be) 25% or more of the voting rights or the right to appoint 25% or more of the directors of the other party, vote against the merger. If, however, the merger involves a merger with a company's own controlling shareholder or if the controlling shareholder has a personal interest in the merger, then the merger is instead subject to the same special majority approval that governs all extraordinary transactions with controlling shareholders.

If the transaction would have been approved by the shareholders of a merging company but for the separate approval of each class or the exclusion of the votes of certain shareholders as provided above, a court may still approve the merger upon the request of holders of at least 25% of the voting rights of a company, if the court holds that the merger is fair and reasonable, taking into account the value of the parties to the merger and the consideration offered to the shareholders of the target company.

Upon the request of a creditor of either party to the proposed merger, the court may delay or prevent the merger if it concludes that there exists a reasonable concern that, as a result of the merger, the surviving company will be unable to satisfy the obligations of the merging entities, and may further give instructions to secure the rights of creditors.

In addition, a merger may not be consummated unless at least 50 days have passed from the date on which a proposal for approval of the merger was filed by each party with the Israeli Registrar of Companies and at least 30 days have passed from the date on which the merger was approved by the shareholders of each party.

Borrowing Powers

Pursuant to the Companies Law and our articles of association, our board of directors may exercise all powers and take all actions that are not required under law or under our articles of association to be exercised or taken by our shareholders, including the power to borrow money for company purposes.

Changes in Capital

Our articles of association enable us to increase or reduce our share capital. Any such changes are subject to the provisions of the Companies Law and must be approved by a resolution duly passed by our shareholders at a general meeting by voting on such change in the capital. In addition, certain transactions that have the effect of reducing capital, such as the declaration and payment of dividends in the absence of sufficient retained earnings or profits, require the approval of both our board of directors and an Israeli court.

Debt Securities

We do not have any debt securities that are registered under Section 12 of the Securities Act.

Warrants and Rights

We do not have any warrants or rights that are registered under Section 12 of the Securities Act.

Other Securities

We do not have any other securities that are registered under Section 12 of the Securities Act.

COLLPLANT BIOTECHNOLOGIES LTD.

INSIDER TRADING POLICY

This Insider Trading Policy (the "**Policy**") sets forth the policy for directors, officers and employees, of Collplant Biotechnologies Ltd. and its subsidiaries (the "**Company**") with respect to transactions in the Company's securities or securities of certain other publicly traded companies while in possession of confidential information.

Applicability of Policy

This Policy applies to all transactions in the Company's Securities, including ordinary shares, preferred shares, restricted shares or units, options and warrants for ordinary shares, bonds and any other securities the Company may issue from time to time, such as convertible debentures and other derivative securities relating to the Company's shares, whether or not issued by the Company, such as exchange-traded options (the "**Company's Securities**"). It applies to all directors, officers and employees of the Company as well as members of their immediate families, members of their households and corporations under their control (collectively, "**Insiders**"). Directors, officers and employees, of the Company are responsible for ensuring that members of their immediate families and members of their households comply with this Policy. This Policy also applies to any person who receives Material Non-Public Information (as defined below) from any Insider.

General Policy

It is against Company policy for any Insider to make an unauthorized disclosure of any nonpublic information acquired in the work-place or as a result of their position with the Company. It is also against Company policy for any Insider to misuse Material Nonpublic Information in securities trading. The Company has established procedures for releasing material information in a manner that is designed to achieve broad public dissemination of the information to the public immediately upon its release. As a director, officer or employee of the Company, you may not, therefore, disclose information to anyone outside the Company, including family members and friends. You also may not discuss the Company or its business in an internet "chat room" or similar internet-based forum.

Specific Policies

1. **Trading on Material Nonpublic Information**

No Insider shall engage in any transaction involving a purchase or sale of the Company's Securities, including any offer to purchase or offer to sell, during any period commencing with the date that he or she possesses Material Nonpublic Information concerning the Company, and ending at the end of trading on the next Trading day following the date of public disclosure of that information, or at such time as such nonpublic information is no longer material. As used herein, the term "**Trading Day**" shall mean a day on which the Nasdaq stock market is open for trading.

Transactions that may be necessary or justifiable for independent reasons (such as the need to raise money for an emergency expenditure) are not excepted from the Policy. The securities laws do not recognize such mitigating circumstances, and, in any event, even the appearance of an improper transaction must be avoided to preserve the Company's reputation for adhering to the highest standards of conduct.

2. **Short Sales**

No Insider shall engage in a short sale of the Company's Securities. A short sale is in general a sale of securities not owned by the seller. Transactions in certain put and call options for the Company's Securities may in some instances constitute a short sale. Short sales may evidence an expectation on the part of the seller that the securities will decline in value, and therefore have the potential to signal to the market that the seller lacks confidence in the Company's prospects. In addition, short sales may reduce a seller's incentive to seek to improve the Company's performance.

3. **Publicly Traded Options**

A transaction in publicly-traded options to purchase or sell the Company's Securities is, in effect, a bet on the short-term movement of the Company's Securities and therefore may create the appearance that the director, officer or employee of the Company is trading based on inside information. Transactions in options also may focus the Insider's attention on short-term performance at the expense of the Company's long-term objectives. Accordingly, transactions in puts, calls or other derivative securities, on an exchange or in any other organized market, by any Insider are prohibited by this Policy. Option positions arising from certain types of hedging transactions are governed by the section below captioned "Hedging Transactions".

4. **Standing Orders**

Standing orders should be used only for a very brief period of time. A standing order placed with a broker to sell or purchase securities at a specified price leaves you with no control over the timing of the transaction. A standing order transaction executed by the broker when you are aware of Material Nonpublic Information may result in unlawful insider trading. Transactions pursuant to a plan adopted in accordance with Rule 10b5-1 of the Securities Exchange Act of 1934, as amended (the "**Exchange Act**"), discussed below, are excepted from this prohibition against standing orders.

5. **Hedging Transactions**

Certain forms of hedging or monetization transactions, such as zero-cost collars and forward sale contracts, allow an employee to lock in much of the value of his or her share holdings, often in exchange for all or part of the potential for upside appreciation in the shares. These transactions allow the Insider to continue to own the securities, but without the full risks and rewards of ownership. When that occurs, Insider may no longer have the same objectives as the Company's other shareholders. As a result, these types of transactions are prohibited by Company policy.

6. **Margin Accounts and Pledges**

Securities held in a margin account may be sold by the broker without the customer's consent if the customer fails to meet a margin call. Similarly, securities pledged (or hypothecated) as collateral for a loan may be sold in foreclosure if the borrower defaults on the loan. A margin or foreclosure sale that occurs when the pledgor is aware of Material Nonpublic Information may, under some circumstances, result in unlawful insider trading. Because of this danger, Insiders should exercise caution in holding the Company's Securities in a margin account or pledging the Company's Securities as collateral for a loan. In addition, certain directors and executive officers may be required to publicly disclose the amount of the Company's Securities pledged as collateral for a loan.

7. **Short-Term Trading**

Short-term trading of the Company's Securities may be distracting to the person and may unduly focus the person on the Company's short-term stock market performance instead of the Company's long-term business objectives. For these reasons, if you purchase or sell Company Securities, you may not conduct an opposite way transaction in any Company Securities of the same class for at least six (6) months after the purchase or sale, unless you first pre-clear the proposed transaction with the Chief Financial Officer.

8. **Tipping**

No Insider shall disclose (commonly known as a "tip") Material Nonpublic Information to any other person (including family members) where such information may be used, or there is a reasonable basis to believe that such information may be used, by such person to his or her profit by trading (buying or selling) in the securities of companies to which such information relates, nor shall such person or related person make recommendations or express opinions on the basis of Material Nonpublic Information as to trading in the Company's Securities.

9. **Advice Concerning Trading**

No Insider may give trading advice of any kind about the Company or the Company's Securities to anyone while possessing Material Nonpublic information about the Company. An Insider should always advise others, preferably in writing or electronically, not to trade in the Company's Securities if doing so might violate any applicable law or this policy. The Company strongly discourages any Insider from giving trading advice concerning the Company's Securities or the Company to third parties even when such persons do not possess Material Nonpublic information about the Company or the Company's Securities.

10. **Confidentiality of Nonpublic Information**

Nonpublic information relating to the Company is the property of the Company and the unauthorized disclosure of such information is forbidden. In the event any Insider receives any inquiry for information from outside the Company, such as from a journalist, stock analyst or investor, the inquiry should be referred to the Company's Chief Executive Officer or to the Chief Financial Officer who is responsible for coordinating and overseeing the release of such information to the investing public, analysts and others in compliance with applicable laws and regulations.

11. **Post-Termination Transactions**

The Policy continues to apply to your transactions in the Company's Securities even after you have terminated employment or cease to serve as an officer, director or employee. If you are in possession of Material Nonpublic Information when your employment or other service to the Company terminates or ceases, you may not trade in the Company's Securities until that information has become public or is no longer material.

Potential Criminal and Civil Liability and/or Disciplinary Action

1. **Liability for Insider Trading**

Pursuant to federal and state securities laws, any person violating U.S. insider trading laws may be subject to penalties of up to $5,000,000 and up to 20 years in jail for engaging in transactions in the Company's Securities at a time when they have knowledge of Material Nonpublic Information regarding the Company.

2. **Liability for Tipping**

Insiders may also be liable for improper transactions by any person (commonly referred to as a "tippee") to whom they have disclosed Material Nonpublic Information regarding the Company or to whom they have made recommendations or expressed opinions on the basis of such information as to trading in the Company's Securities. The Securities and Exchange Commission (the "**SEC**") has imposed large penalties even when the disclosing person did not profit from the trading. The SEC, the stock exchanges, the Financial Industry Regulatory Authority and the Israeli Securities Authority use sophisticated electronic surveillance techniques to uncover insider trading. In recent years, criminal prosecution of insiders has become much more common, particularly when such persons were aware of their obligations under the securities laws and elected to ignore those obligations in acting on, or in tipping others concerning, Material Nonpublic Information.

3. **Liability of Control Persons**

If the Company or its supervisory personnel fail to take appropriate steps to prevent illegal insider trading, they may be subject to the following penalties:

(a) A civil penalty of up to $1,425,000 or, if greater, three times the profit gained or loss avoided as a result of the employee's violation; and

(b) A criminal penalty of up to $5,000,000 and up to 20 years in jail for individuals and/or a fine of $25,000,000 for the Company.

4. **Possible Disciplinary Actions**

Insiders who violate this Policy may also be subject to disciplinary action by the Company, which may include ineligibility for future participation in the Company's equity incentive plans and/or termination of employment.

Trading Guidelines and Requirements

1. **Black-Out Periods and Trading Window**

a. ***Financial Black-Out Period.*** The period beginning 30 days prior to the date of public disclosure of the financial results and ending at the end of the trading on the next Trading Day after the date of public disclosure of the financial results. The sensitivity arises because directors, officers and certain employees involved in the preparation of the financial results will often possess Material Nonpublic Information about the expected financial results for the quarter during that period. Accordingly, this period of time is referred to as a "financial black-out" period. Accordingly, all officers, directors and employees are prohibited from trading during such period.

b. ***Clinical Information Black-Out Period.*** It is common for life science companies to come into possession of information concerning (i) the early results of clinical trials of product candidates, (ii) reported results of clinical trials of product candidates from Company personnel or from contractors, and/or (iii) information that results from the analyses of clinical trial results pertaining to product candidates. This information is highly sensitive due to the fact that certain Insiders may possess Material Nonpublic Information concerning the early results of the clinical trials, the yet-unreported results of the clinical trials, or the scientific or medical inferences or conclusions that can be drawn from the early results or yet-unreported results of clinical trials. The periods of time during which the Company has received (i) information concerning the early results of clinical trials of product candidates, (ii) reported results of clinical trials of product candidates from Company personnel or contractors, and/or (iii) information that results from the analyses of clinical trial results pertaining to product candidates, are referred to as "clinical information black-out periods". All directors and officers (and those other Insiders identified by the Company from time to time and who have been notified that they have been so identified) are prohibited from trading in the Company's Securities during clinical information black-out periods and should not disclose to others the fact of such suspension of trading.

c. ***Special Black-Out Periods.*** In addition, from time to time Material Nonpublic Information regarding the Company may be pending or there may be material developments known to the Company and not yet disclosed to the public. The Company may impose a special "black-out" period on all directors and officers (and those other Insiders identified by the Company from time to time and who have been notified that they have been so identified) prohibiting them from trading in the Company's Securities during a special black-out period and such persons should not disclose to others the fact of such suspension of trading.

d. ***Mandatory Trading Window Related to Financial Information.*** To ensure compliance with this Policy and applicable federal and state securities laws, the Company requires that all Insiders refrain from conducting transactions involving the purchase or sale of the Company's Securities other than during the period (the "**Trading Window**") commencing at the open of market on the second Trading Day following the date of public disclosure of the financial results for a particular fiscal quarter or year and continuing until the close of market on the 30 days prior to the date of public disclosure of the financial results. During the Trading Window, if the Company is in a clinical information black-out period or special black-out period, the Company requires that all directors, officers, employees and those certain identified Insiders refrain from conducting transactions involving the purchase or sale of the Company's Securities even though the Trading Window may otherwise be open. The prohibition against trading during the financial black-out period, clinical information black-out period and special black-out period encompasses the fulfillment of "limit orders" by any broker for an Insider and the brokers with whom any such limit order is placed must be so instructed at the time it is placed.

It should be noted, however, that even during a Trading Window, any person possessing Material Nonpublic Information concerning the Company, whether or not subject to the financial, clinical information or special black-out periods, should not engage in any transactions in the Company's Securities (except for transactions specifically described in the "Certain Exceptions" section below) until such information has been known publicly for at least one full Trading Day, whether or not the Company has recommended a suspension of trading to that person. Trading in the Company's Securities during the Trading Window is not a "safe harbor," and all Insiders should use good judgment at all times and pre-clear all trades in accordance with the following paragraph.

2. **Pre-Clearance of Trades**

All Insiders must refrain from trading in the Company's Securities without first complying with the Company's "pre-clearance" process, even if the trade would take place in a Trading Window. Each Insider must contact the Chief Financial Officer prior to commencing any trade in the Company's Securities. The Chief Financial Officer will consult as necessary with senior management and/or directors of the Company before clearing any proposed trade.

3. **Individual Responsibility**

Every Insider has the individual responsibility to comply with this Policy. He or she may, from time to time, have to forego a proposed transaction in the Company's Securities even if he or she planned to make the transaction before learning of the Material Nonpublic Information and even though he or she believes he or she may suffer an economic loss or forego anticipated profit by waiting.

As part of your individual responsibility, you should take every practicable step to preserve the confidentiality of information. For example:

(a) Don't discuss material information in elevators, hallways, restaurants, airplanes, taxicabs or any place where you can be overheard;

(b) Don't gossip about confidential information;

(c) Don't read confidential documents in public places or discard them where they can be retrieved by others;

(d) Don't carry confidential documents in elevators, hallways, etc. in an exposed manner;

(e) Beware of the carrying quality of conversations conducted on speaker telephones in offices, and the potential for eavesdropping on conversations conducted on car or airplane telephones, on marine radios etc;

(f) Don't leave confidential documents in unattended conference rooms; don't leave confidential documents behind when the conference is over;

(g) Cover confidential documents on your desk before you leave your room; don't leave confidential papers lying where visitors can see them;

(h) Be careful when giving out the whereabouts of personnel not in the office or revealing the presence of specific visitors to the office. The mere fact of a meeting or the destination of a trip may reveal something confidential; and

(i) Under no circumstances are employees to provide confidential Company documents and information or other information to third parties, without express consent of the supervisor. This includes, but is not limited to, any confidential Company documents or information relating to customers, competitors or suppliers of the Company.

(j) Obviously, a list such as this can only be suggestive. It is the responsibility of each employee to take whatever practicable steps are appropriate to preserve the confidentiality of information.

Applicability of Policy to Inside Information Regarding Other Companies

This Policy also applies to Material Nonpublic Information relating to other companies with which the Company conducts business, including proposed business combinations ("**Business Partners**"), when that information is obtained in the course of employment with, or other services performed on behalf of, the Company. Civil and criminal penalties, and termination of employment, may result from trading on inside information regarding the Company's Business Partners. All Insiders should treat Material Nonpublic Information about the Company's Business Partners with the same care required with respect to information related directly to the Company. Similarly, you must not discuss Material Nonpublic Information relating to the Company's Business Partners in an internet "chat room" or similar internet-based forum.

Definition of "Material Nonpublic Information"

It is not possible to define all categories of Material Nonpublic Information. However, information should be regarded as material if there is a reasonable likelihood that it would be considered important (within the total mix of information) to an investor in making an investment decision regarding the purchase or sale of the Company's Securities. Either positive or negative information may be material.

While it may be difficult under this standard to determine whether particular information is material, there are various categories of information that are particularly sensitive and, as a general rule, should always be considered material. Examples of such information may include:

(a) financial results;

(b) news of major clinical or development milestones;

(c) early indications of clinical trial results;

(d) known but unannounced clinical trial results;

(e) known but unannounced analyses of clinical trial results;

(f) significant communications to or from regulatory agencies, or other significant regulatory developments;

(g) significant developments related to intellectual property;

(h) significant developments related to collaboration and other business relationships;

(i) proposals, plans or agreements, even if preliminary in nature, involving mergers, acquisitions, divestitures, recapitalizations, strategic alliances, licensing arrangements, or purchases or sales of substantial assets;

(j) impending bankruptcy or financial liquidity problems;

(k) share splits;

(l) new equity or debt offerings;

(m) positive or negative developments in outstanding litigation;

(n) significant litigation exposure due to actual or threatened litigation; and

(o) changes in senior management, the Company's auditors or the board of directors.

Nonpublic information is information that has not been previously disclosed to the general public and is otherwise not available to the general public. To be "public" the information must have been disseminated in a manner designed to reach investors generally, and the investors must be given the opportunity to absorb the information.

Certain Exceptions

1. **Share Option Exercises**

The Company's Policy does not apply to the exercise of an Insider share option if the shares acquired upon exercise are held rather than sold, or to the exercise of a tax withholding right pursuant to the option holder elects to have the Company withhold shares subject to an option to satisfy tax withholding requirements. The Policy does apply, however, to any sale of shares as part of a broker-assisted cashless exercise of an option, or any other sale for the purpose of generating the cash needed to pay the exercise price of an option.

2. **Restricted Share Awards**

This Policy does not apply to the vesting of restricted shares, or the forfeiture of shares to pay for taxes incident to such vesting.

3. **Gifts**

Bona fide gifts of the Company's Securities generally may be exempt from this Policy. However, all such gifts by Insiders must be pre-cleared by the Chief Financial Officer if a Black-Out Period is in effect at the time of the gift. The Chief Financial Officer may prohibit any gift that is subject to pre-clearance in his or her sole discretion.

4. **Blind Trusts and Pre-Arranged Trading Programs**

Rule 10b5-1 of the Exchange Act provides an affirmative defense against insider trading liability for a transaction done pursuant to "blind trusts" (trusts in which investment control has been delegated to a third party, such as an institutional or professional trustee) or pursuant to a written plan, or a binding contract or instruction, entered into in good faith at a time when the Insider was not aware of Material Nonpublic Information, even though the transaction in question may occur at a time when such person is aware of Material Nonpublic Information.

The Company may, in appropriate circumstances, permit Insiders to enter into a blind trust or a trading program that complies with Rule 10b5-1, in which case, unless otherwise determined as provided below, the pre-clearance procedures or the Black-Out Periods of this Policy shall not apply to transactions executed pursuant to such blind trust or trading program. All blind trusts and trading programs, must be pre-cleared with the Chief Financial Officer. With respect to arrangements that result or may result in transactions taking place during Black-Out Periods, the Chief Financial Officer will review such arrangements in light of guidelines that it from time to time establishes, with input, if appropriate, from the Board of Directors and Company legal counsel. The Company reserves the right to bar any transactions in the Company's Securities, including transactions pursuant to arrangements previously approved, if the Chief Financial Officer determines that such a bar is in the best interests of the Company. In addition, the Company does not permit any trades in such a blind trust or a Rule 10b5-1 trading program to consist of any hedging transactions (as described above).

Priority of Statutory or Regulatory Trading Restrictions

The trading prohibitions and restrictions set forth in this Policy will be superseded by any greater prohibitions or restrictions prescribed by federal or state securities laws and regulations, e.g., contractual restrictions on the sale of securities (e.g. under lock-up agreements), short-swing trading by Section 16 parties (if applicable) or restrictions on the sale of securities subject to Rule 144 under the Securities Act. Any person who is uncertain whether other prohibitions or restrictions apply should ask the Chief Financial Officer.

Inquiries

Any person who has a question about this Policy or its application to any proposed transaction may obtain additional guidance from the Chief Financial Officer. Ultimately, however, the responsibility for adhering to this Policy and avoiding unlawful transactions rests with the individual Insider.

Certifications

All directors, officers and employees must certify their understanding of, and intent to comply with, this Policy. Please sign the certification attached hereto.

Policy Last Updated: July 2020

COLLPLANT INSIDER TRADING POLICY

Certification

I certify that:

1. I have read and understand the Insider Trading Policy of CollPlant. I understand that the Chief Financial Officer is available to answer any questions I have regarding the Policy.

2. Since the date this Policy became effective, or such shorter period of time that I have been a director, officer or other employee of the Company, I have complied with the Policy.

3. I will continue to comply with the Policy for as long as I am subject to the Policy.

Employee's Signature	Employee's Name [printed]
Position	Date

Exhibit 12.1

CERTIFICATION OF THE CHIEF EXECUTIVE OFFICER UNDER SECTION 302 OF
THE SARBANES-OXLEY ACT

I, Yehiel Tal, certify that:

1. I have reviewed this annual report on Form 20-F of CollPlant Biotechnologies Ltd.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the company as of, and for, the periods presented in this report;

4. The company's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the company and have:

- Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

- Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

- Evaluated the effectiveness of the company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

- Disclosed in this report any change in the company's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the company's internal control over financial reporting; and

5. The company's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the company's auditors and the audit committee of the company's board of directors (or persons performing the equivalent functions):

- All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the company's ability to record, process, summarize and report financial information; and

- Any fraud, whether or not material, that involves management or other employees who have a significant role in the company's internal control over financial reporting.

Date: March 26, 2025

/s/ Yehiel Tal
Yehiel Tal
Chief Executive Officer

Exhibit 12.2

CERTIFICATION OF THE CHIEF FINANCIAL OFFICER UNDER SECTION 302 OF
THE SARBANES-OXLEY ACT

I, Eran Rotem, certify that:

1. I have reviewed this annual report on Form 20-F of CollPlant Biotechnologies Ltd.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the company as of, and for, the periods presented in this report;

4. The company's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the company and have:

- Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

- Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

- Evaluated the effectiveness of the company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

- Disclosed in this report any change in the company's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the company's internal control over financial reporting; and

5. The company's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the company's auditors and the audit committee of the company's board of directors (or persons performing the equivalent functions):

- All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the company's ability to record, process, summarize and report financial information; and

- Any fraud, whether or not material, that involves management or other employees who have a significant role in the company's internal control over financial reporting.

Date: March 26, 2025

/s/ Eran Rotem
Eran Rotem
Chief Financial Officer

Exhibit 13.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER UNDER SECTION 906 OF THE
SARBANES-OXLEY ACT

Pursuant to 18 U.S.C. Section 1350, as created by Section 906 of the Sarbanes-Oxley Act of 2002, the undersigned officer of CollPlant Biotechnologies Ltd. (the "Company") hereby certifies to such officer's knowledge that:

(i) the accompanying Annual Report on Form 20-F of the Company for the year ended December 31, 2024 (the "Report") fully complies with the requirements of Section 13(a) or Section 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and

(ii) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: March 26, 2025

/s/ Yehiel Tal
Yehiel Tal
Chief Executive Officer

The foregoing certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. Section 1350, and is not being filed for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference to any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Exhibit 13.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER UNDER SECTION 906 OF THE
SARBANES-OXLEY ACT

Pursuant to 18 U.S.C. Section 1350, as created by Section 906 of the Sarbanes-Oxley Act of 2002, the undersigned officer of CollPlant Biotechnologies Ltd. (the "Company") hereby certifies to such officer's knowledge that:

(i) the accompanying Annual Report on Form 20-F of the Company for the year ended December 31, 2024 (the "Report") fully complies with the requirements of Section 13(a) or Section 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and

(ii) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: March 26, 2025

/s/ Eran Rotem
Eran Rotem
Chief Financial Officer

The foregoing certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. Section 1350, and is not being filed for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference to any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Exhibit 15.1

Kost Forer Gabbay & Kasierer
144 Menachem Begin Road, Building A
Tel-Aviv 6492102, Israel

Tel: +972-3-6232525
Fax: +972-3-5622555
ey.com

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the following Registration Statements:

(1) Registration Statements (Form F-3 No. 333-238731 and 333-269087) of CollPlant Biotechnologies Ltd., and

(2) Registration Statements (Form S-8 No. 333-229163, 333-248479, 333-263842, and 333-271320) pertaining to the Share Ownership and Option Plan (2010) of CollPlant Biotechnologies Ltd.; and

(3) Registration Statement (Form S-8 No. 333-279791) pertaining to the 2024 Share Award Plan of CollPlant Biotechnologies Ltd.

of our reports dated March 26, 2025, with respect to the consolidated financial statements of CollPlant Biotechnologies Ltd. included in this Annual Report (Form 20-F) of CollPlant Biotechnologies Ltd. for the year ended December 31, 2024.

/s/ Kost Forer Gabbay & Kasierer
Kost Forer Gabbay & Kasierer
A Member of EY Global

Tel Aviv, Israel
March 26, 2025